

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, 415, 419, 495, and 512

[CMS-1849-P]

RINs 0938-AV79

## Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; and Other Policy Changes

**AGENCY:** Centers for Medicare & Medicaid Services (CMS) and Department of Health and Human Services (HHS).

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals; make changes relating to Medicare graduate medical education (GME) for teaching hospitals; update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs); update and make changes to requirements for certain quality programs; and make other policy-related changes.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided in the

**ADDRESSES** section, no later than 5 p.m. EDT on April 10, 2026.

**ADDRESSES:** In commenting, please refer to file code CMS-1849-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the instructions under the “submit a comment” tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention:

CMS-1849-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1849-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

### FOR FURTHER INFORMATION CONTACT:

Donald Thompson, and Michele Hudson, (410) 786-4487 or [DAC@cms.hhs.gov](mailto:DAC@cms.hhs.gov), Operating Prospective Payment, MS-DRG Relative Weights, Wage Index, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Sole Community Hospitals (SCHs), Medicare-Dependent Small Rural Hospital (MDH) Program, and Low-Volume Hospital Payment Adjustment.

Emily Lipkin, Jim Milenderberger and Michael Raftery, [DAC@cms.hhs.gov](mailto:DAC@cms.hhs.gov), Long-Term Care Hospital Prospective Payment System and MS-LTC-DRG Relative Weights Issues.

Lily Yuan, [NewTech@cms.hhs.gov](mailto:NewTech@cms.hhs.gov), New Technology Add-On Payments Issues.

Mady Hue, [marilu.hue@cms.hhs.gov](mailto:marilu.hue@cms.hhs.gov), and Andrea Hazeley, [andrea.hazeley@cms.hhs.gov](mailto:andrea.hazeley@cms.hhs.gov), MS-DRG Classifications Issues.

David O'Reilly, [David.Oreilly@cms.hhs.gov](mailto:David.Oreilly@cms.hhs.gov), Rural Community Hospital Demonstration Program Issues.

Jeris Smith, [jeris.smith@cms.hhs.gov](mailto:jeris.smith@cms.hhs.gov), Frontier Community Health Integration Project (FCHIP) Demonstration Issues.

Lang Le, [lang.le@cms.hhs.gov](mailto:lang.le@cms.hhs.gov), Hospital Readmissions Reduction Program and Hospital Acquired Condition Reduction Program—Administration Issues.

Ngozi Uzokwe, [ngozi.uzokwe@cms.hhs.gov](mailto:ngozi.uzokwe@cms.hhs.gov), Hospital Acquired Condition Reduction Program and Hospital Readmissions Reduction Program—Measures Issues.

Julia Venzani, [julia.venanzi@cms.hhs.gov](mailto:julia.venanzi@cms.hhs.gov), Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Administration Issues.

Melissa Hager, [melissa.hager@cms.hhs.gov](mailto:melissa.hager@cms.hhs.gov), and Ngozi Uzokwe,

[ngozi.uzokwe@cms.hhs.gov](mailto:ngozi.uzokwe@cms.hhs.gov)—Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

John Green, [john.green1@cms.hhs.gov](mailto:john.green1@cms.hhs.gov), PPS-Exempt Cancer Hospital Quality Reporting Program—Administration Issues.

Kristina Rabarison, [Kristina.Rabarison@cms.hhs.gov](mailto:Kristina.Rabarison@cms.hhs.gov), PPS-Exempt Cancer Hospital Quality Reporting Program—Measure Issues.

Ariel Cress, [Ariel.Cress@cms.hhs.gov](mailto:Ariel.Cress@cms.hhs.gov), Long-Term Care Hospital Quality Reporting Program—Administration Issues.

Jessica Warren, [jessica.warren@cms.hhs.gov](mailto:jessica.warren@cms.hhs.gov), and Lisa Marie Gomez, [LisaMarie.Gomez1@cms.hhs.gov](mailto:LisaMarie.Gomez1@cms.hhs.gov), Medicare Promoting Interoperability Program.

[CMMI\\_TEAM@cms.hhs.gov](mailto:CMMI_TEAM@cms.hhs.gov), Transforming Episode Accountability Model (TEAM).

[CJR-X@cms.hhs.gov](mailto:CJR-X@cms.hhs.gov), Comprehensive Care for Joint Replacement Expanded (CJR-X) Model.

Katherine McDonald, [katherine.mcdonald@cms.hhs.gov](mailto:katherine.mcdonald@cms.hhs.gov), Amanda Michael, [amanda.michael@cms.hhs.gov](mailto:amanda.michael@cms.hhs.gov), and Kellie Shannon, [kellie.shannon@cms.hhs.gov](mailto:kellie.shannon@cms.hhs.gov), Organ Acquisition Payment, Reasonable Cost Payment, and Appeals for Independent Organ Procurement Organizations (IOPOs) and Histocompatibility Laboratories (HCLs).

### SUPPLEMENTARY INFORMATION:

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on [Regulations.gov](https://www.regulations.gov) public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

*Plain Language Summary:* In accordance with 5 U.S.C. 553(b)(4), a

plain language summary of this rule may be found at <https://www.regulations.gov/>.

#### Tables Available on the CMS Website

The IPPS tables for this fiscal year (FY) 2027 proposed rule are available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. Click on the link on the left side of the screen titled “FY 2027 IPPS Proposed Rule Home Page” or “Acute Inpatient—Files for Download.” The LTCH PPS tables for this FY 2027 proposed rule are available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html> under the list item for Regulation Number CMS–1849–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this FY 2027 IPPS/LTCH PPS proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact Michael Treitel, [DAC@cms.hhs.gov](mailto:DAC@cms.hhs.gov).

### I. Executive Summary and Background

#### A. Executive Summary

##### 1. Purpose and Legal Authority

This FY 2027 IPPS/LTCH PPS proposed rule would make payment and policy changes under the Medicare inpatient prospective payment system (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This proposed rule also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. We are also proposing to make changes relating to Medicare graduate medical education (GME) and nursing and allied health (NAH) education payments.

We are proposing to adopt the Advance Care Planning electronic clinical quality measure (eCQM) in the Hospital Inpatient Quality Reporting, PPS-Exempt Cancer Hospital (PCH) Quality Reporting, and Medicare Promoting Interoperability Programs. We are proposing to adopt five modified claims-based, risk-standardized mortality measures in the Hospital Inpatient Quality Reporting Program

and subsequently modify these measures in the Hospital Value-Based Purchasing Program.

Other than these cross-program proposals, we are not proposing any updates for the Hospital Value-Based Purchasing Program or the Hospital Acquired-Conditions Reduction Program.

In the Hospital Readmissions Reduction Program, we are proposing to adopt the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure.

In addition to the cross-program proposals previously listed, in the Hospital Inpatient Quality Reporting Program, we are proposing to adopt two new quality measures, remove three measures, and modify three current measures. We are also proposing to modify the data reporting and submission requirements for electronic clinical quality measures (eCQMs) and the Maternal Morbidity structural measure.

In addition to the cross-program proposal previously listed in the PCH Quality Reporting Program, we are proposing to adopt one new measure and remove one measure. We are also proposing to adopt data reporting and submission requirements for eCQMs.

In addition to the cross-program proposal previously listed, in the Medicare Promoting Interoperability Program, we propose to remove two measures and two attestations; adopt a measure; modify one measure; adopt one additional eCQM in alignment with the Hospital Inpatient Quality Reporting Program; and remove three eCQMs in alignment with the Hospital Inpatient Quality Reporting Program.

In the LTCH Quality Reporting Program (QRP), we are proposing to remove two measures, beginning with the FY 2028 LTCH QRP. We also propose the revision of the LTCH QRP Data Submission Deadlines beginning with the FY 2029 LTCH QRP. Finally, we are soliciting public comments on one Request for Information (RFI) on future measure concepts for the LTCH QRP.

The Transforming Episode Accountability Model (TEAM), a mandatory alternative payment model that was finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), aims to improve beneficiary care through financial accountability for episodes categories that begin with one of the following procedures: coronary artery bypass graft (CABG), lower extremity joint replacement (LEJR), major bowel procedure, surgical hip/femur fracture treatment (SHFFT), and

spinal fusion. TEAM tests whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. In this proposed rule, we propose updates to TEAM that would modify policies affecting episode category triggers, quality measure assessment, and the construction of target prices. Additionally, we are soliciting public feedback on two Request for Information (RFIs) regarding ambulatory surgical center episodes and voluntary participation of hospitals with physician ownership.

The Comprehensive Care for Joint Replacement CJR Expanded (CJR–X) Model builds upon the CJR Model test that ran from April 1, 2016 to December 31, 2024. Based on the strength of evidence from the CJR Model, the CMS Innovation Center is proposing to expand the model nationally, including U.S. Territories in FY 2028. The model would continue to focus on improving care and reducing spending for Medicare beneficiaries undergoing lower extremity joint replacement (LEJR) procedures. Participating hospitals would be held accountable for spending and quality of care during an inpatient stay or hospital outpatient procedure and for the 90 days following hospital discharge. If finalized, the CJR–X Model would be mandatory for acute care hospitals, except for those participating in TEAM, and acute care hospitals located in Maryland. CJR–X would include some modifications to the CJR Model. Some quality measures and payment methodology policies have been updated in response to CJR Model evaluation results, stakeholder feedback, and changes to national care delivery patterns among both CJR and non-CJR hospitals.

Under various statutory authorities, we either discuss continued program implementation or propose changes to the Medicare IPPS, the LTCH PPS, other related payment methodologies and programs for FY 2027 and subsequent fiscal years, and other policies and provisions included in this proposed rule. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).

- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals; and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.

- Sections 123(a) and (c) of the Balanced Budget Refinement Act of 1999 (BBRA) (Public Law (Pub. L.) 106–113) and section 307(b)(1) of the Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.

- Section 1814(l)(4) of the Act requires, beginning with FY 2015, that CAHs that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for an EHR reporting period for a cost reporting period shall be paid 100 percent of reasonable costs rather than 101 percent of reasonable costs.

- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. Hospitals paid under the IPPS with approved GME programs are paid for the indirect costs of training residents in accordance with section 1886(d)(5)(B) of the Act.

- Section 1886(d)(5)(F) of the Act provides for additional Medicare IPPS payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. These payments are known as the Medicare disproportionate share hospital (DSH) adjustment. Section 1886(d)(5)(F) of the Act specifies the methods under which a hospital may qualify for the DSH payment adjustment.

- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a

subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.

- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to DSH payments under section 1886(d)(5)(F) of the Act and for an additional uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act if subsection (r) did not apply (“the empirically justified amount”); and (2) an additional payment for the DSH hospital’s proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act, in the absence of section 1886(r) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) the hospital’s uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.

- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2027.

- Section 1899B of the Act, which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.

- Section 1886(b)(3)(B)(viii) of the Act, which establishes the Hospital Inpatient Quality Reporting Program, requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges

occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.

- Section 1886(b)(3)(B)(ix) of the Act, which establishes payment adjustments under the Medicare Promoting Interoperability Program by requiring downward adjustments to the applicable percentage increase, beginning with FY 2015 (and beginning with FY 2022 for subsection (d) Puerto Rico hospitals), for eligible hospitals that do not successfully demonstrate meaningful use of CEHRT for an EHR reporting period for a payment adjustment year. Additionally, Section 1886(n) of the Act establishes the requirements for an eligible hospital to be treated as a meaningful EHR user of CEHRT for an EHR reporting period for a payment adjustment year or, for purposes of subsection (b)(3)(B)(ix) of the Act, for a fiscal year.

- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as “PPS—exempt cancer hospitals.”

- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year.

- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.

- Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act directs the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries in determining the extent of excess readmissions.

- Section 1886(m)(5) of the Act, which requires the Secretary to reduce by 2 percentage points the annual update to the standard Federal rate for discharges for a long-term care hospital (LTCH) during the rate year for LTCHs that do not submit data on quality

measures in the form, manner, and at a time, specified by the Secretary.

- Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries while reducing program expenditures.

## 2. Summary of the Major Provisions

The following is a summary of the major provisions in this proposed rule. In general, these major provisions are being proposed as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the changes in this proposed rule is presented in section I.D. of the preamble of this proposed rule.

### a. Proposed Requirements To Prohibit Unlawful Discrimination by Graduate Medical Education Programs and Nursing and Allied Health Education Programs

In section V.F.2. of the preamble of this proposed rule, we discuss our proposal to require that, in addition to meeting other applicable requirements, an approved medical residency training program must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. In V.G.3. of the preamble of this proposed rule, we discuss similar proposals with respect to approved nursing and allied health education programs and accreditors.

### b. Proposed Modifications to the Criteria for New Residency Programs

In section V.F.3. of the preamble of this proposed rule, we discuss our proposed modifications to the criteria for identifying new residency programs under 42 CFR 413.79(l). We propose that, in addition to receiving initial accreditation by the appropriate accrediting body, for a residency program to be considered new, at least 90 percent of the individual residents must not have previous experience training in another program in the same specialty. The proposed requirement includes exceptions for small residency programs, displaced residents, and residents admitted via a binding third-party matching program. In determining

whether a program is genuinely new for cap-building purposes, we would also no longer consider the previous employment of the program director or faculty.

### c. Hospital Readmissions Reduction Program (HRRP)

In this FY 2027 IPPS/LTCH PPS proposed rule, we are proposing to adopt the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure beginning with an early look for the FY 2028 program year, and use beginning with the FY 2029 program year.

### d. Hospital Value-Based Purchasing (VBP) Program

In this FY 2027 IPPS/LTCH PPS proposed rule, we are proposing modifications to five condition-specific and procedure-specific mortality measures beginning with the FY 2032 program year: (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization measure; (2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization measure; (3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure; (4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization measure; and (5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery measure. We also include requests for information on two topics: (1) measuring emergency room access and timeliness in Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs; (2) potential future use of the Adult Community-Onset Sepsis Standardized Mortality Ratio measure in the Hospital Inpatient Quality Reporting Program.

### e. Hospital Inpatient Quality Reporting Program

In this FY 2027 IPPS/LTCH PPS proposed rule, we are proposing several changes to the Hospital Inpatient Quality Reporting Program. We are proposing to adopt three new measures: (1) Excess Days in Acute Care After Hospitalization for Diabetes measure beginning with the FY 2029 payment determination; (2) Advance Care Planning eCQM beginning with the FY 2030 payment determination; (3) Hospital Harm-Postoperative Venous Thromboembolism eCQM beginning with the FY 2030 payment

determination. We are also proposing to adopt five modified mortality measures in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination before subsequently modifying them in the Hospital Value-Based Purchasing Program: (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization measure; (2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization measure; (3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure; (4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization measure; and (5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery measure. We are proposing modifications to three claims-based measures beginning with the FY 2028 payment determination: (1) Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction; (2) Excess Days in Acute Care after Hospitalization for Heart Failure; and (3) Excess Days in Acute Care after Hospitalization for Pneumonia. We are proposing to remove three measures: (1) Venous Thromboembolism Prophylaxis (VTE-1) eCQM; (2) Intensive Care Unit Venous Thromboembolism Prophylaxis (VTE-2) eCQM; and (3) Discharged on Antithrombotic Therapy (STK-02) eCQM beginning with the FY 2030 payment determination. We are also proposing changes to data reporting and submission requirements for eCQMs and structural measures: (1) mandatory reporting for the Malnutrition Care Score eCQM beginning with the FY 2030 payment determination; (2) mandatory reporting for the Hospital Harm eCQMs after 2 years of self-selected reporting beginning with the FY 2030 payment determination; and (3) an update to the reporting of the Maternal Morbidity Structural measure beginning with the FY 2028 payment determination. We also include requests for information on three topics: (1) measuring emergency room access and timeliness in Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs; (2) potential future use of the Adult Community-Onset Sepsis Standardized Mortality Ratio measure in the Hospital Inpatient Quality Reporting Program; and (3) Birthing-Friendly Hospital designation modification to expand designation criteria.

f. PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program

In this FY 2027 IPPS/LTCH PPS proposed rule, we are proposing to adopt two new measures: (1) Advance Care Planning eCQM beginning with the FY 2030 program year; and (2) Malnutrition Care Score eCQM beginning with the FY 2030 program year. We are also proposing to remove the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP COVID-19 Vaccination) measure beginning with the FY 2028 program year. In addition, we propose establishing reporting and submission requirements for eCQMs in this program.

g. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In the LTCH QRP, we are proposing to remove two measures, beginning with the FY 2028 LTCH QRP. We also propose the revision of the LTCH QRP Data Submission Deadlines beginning with the FY 2029 LTCH QRP. We are also soliciting public comments on one Request for Information (RFI) on future measure concepts for the LTCH QRP.

h. Medicare Promoting Interoperability Program

We are proposing several changes to the Medicare Promoting Interoperability Program. Specifically, we are proposing: (1) to revise the definition of certified EHR technology (CEHRT) for the Medicare Promoting Interoperability Program based on Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) proposals to update the ONC Health IT Certification Program; (2) to remove attestations related to ONC Direct Review and ONC-Authorized Certification Body (ONC-ACB) Surveillance; (3) to remove the Support

Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure; (4) to modify the Electronic Prior Authorization measure; (5) to adopt the Unique Device Identifiers (UDIs) for Implantable Medical Devices measure within the Public Health and Clinical Data Exchange objective; (6) to adopt two new eCQMs in alignment with the Hospital Inpatient Quality Reporting Program; and (7) to remove three eCQMs in alignment with the Hospital Inpatient Quality Reporting Program.

i. Transforming Episode Accountability Model (TEAM)

In section X.A. of the preamble of this proposed rule, we discuss the changes we propose for the Transforming Episode Accountability Model (TEAM). TEAM is a 5-year mandatory model tested under the authority of section 1115A of the Act, that started on January 1, 2026, and will end on December 31, 2030. We propose changes to a few areas of the model, including: (1) adding X Medicare Severity Diagnosis Related Groups (MS-DRGs) that would initiate a spinal fusion anchor hospitalization; (2) clarifying quality measure performance periods for certain quality measures; (3) using a rolling historical Composite Quality Score (CQS) baseline period for certain quality measures; (4) adding an Ambulatory Payment Classification (APC) and MS-DRG update factor to target prices; and (5) using the full baseline period to construct the prospective normalization factor. We are also soliciting feedback on two Request for Information (RFIs) for ambulatory surgical center episodes and potential voluntary participation of physician owned hospitals in future years of the model.

j. Comprehensive Care for Joint Replacement Expanded (CJR-X) Model

In section X.C. of the preamble of this proposed rule, we propose expansion of the CJR Model. The CJR-X Model would be a mandatory model that would be tested under the authority of section 1115A of the Act, beginning on October 1, 2027 for acute care hospitals paid under the IPPS and OPPS with limited exclusions. Participating hospitals would be accountable for the cost and quality of care for LEJR episodes from the hospital inpatient or hospital outpatient admission through 90 days after the beneficiary is discharged from the hospital or hospital outpatient procedure. We propose multiple policies for CJR-X, including: (1) an October 1, 2027 start date; (2) acute care hospitals as the participant and accountable entity; (3) LEJR as the episode of care; (4) five quality measures and a composite quality score (CQS) to assess quality performance; (5) regional risk-adjusted target prices that include capped normalization and trend factors; (6) pricing-specific policies for certain hospitals, such as low volume hospitals and high duals hospitals; (7) provider and beneficiary overlap permitted with most models; (8) allowing participant hospitals to have financial arrangements; (9) waiving certain Medicare Program requirements; (10) permitting beneficiary-identifiable and regional aggregated data sharing; and (11) options for Alternative Payment Model (APM) participation.

3. Summary of Costs and Benefits

The following table provides a summary of the costs, savings, and benefits associated with the major provisions described in section I.A.2. of the preamble of this proposed rule.

**BILLING CODE 4120-01-P**

| Provision Description                                                                                                                             | Description of Costs, Transfers, Savings, and Benefits                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Proposed Update to the IPPS Payment Rates and Other Payment Policies                                                                              | As discussed in Appendix A of this proposed rule, acute care hospitals are estimated to experience a \$1.9 billion increase in payments in FY 2027, primarily driven by the changes in FY 2027 operating payments, including outlier payments, uncompensated care payments, capital payments, new technology add-on payments, and the expiration of the temporary changes in the low-volume hospital program and the expiration of the MDH program on January 1, 2027.                                                                                                                                                                          |
| Proposed Update to the LTCH PPS Payment Rates and Other Payment Policies                                                                          | As discussed in Appendix A of this proposed rule, based on the best available data for the 318 LTCHs in our analysis, we estimate that the changes to the payment rates and factors that we present in the preamble of and Addendum of this proposed rule, which reflect the update to the LTCH PPS standard federal payment rate for FY 2027, would result in an estimated increase in payments in FY 2027 of approximately \$55 million.                                                                                                                                                                                                      |
| Proposed Requirements to Prohibit Unlawful Discrimination by Graduate Medical Education Programs and Nursing and Allied Health Education Programs | As discussed in Appendix A of this proposed rule, regarding our proposals concerning unlawful discrimination by approved programs and accrediting bodies, as of October 1, 2026, we do not expect that approved programs or accrediting bodies would continue to or newly engage in unlawful discrimination on the basis of race or other protected characteristics.                                                                                                                                                                                                                                                                            |
| Changes to the Hospital Readmissions Reduction Program                                                                                            | We estimated that our changes for the Hospital Readmissions Reduction Program will result in no financial impact for the FY 2027 payment determination.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Changes to the Value-based Incentive Payments under the Hospital Value-Based Purchasing Program                                                   | We estimate that there will be no net financial impact to the Hospital Value-Based Purchasing Program for the FY 2027 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS-DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS-DRG payment amount reductions for the FY 2027 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2027 discharges is approximately \$1.9 billion. |
| Changes to the Hospital IQR Program                                                                                                               | Across 3,050 IPPS hospitals, we estimate that our changes for the Hospital Inpatient Quality Reporting Program will result in an increase of 8,133 hours and \$447,803 to the information collection burden for the FY 2030 payment determination and subsequent years.                                                                                                                                                                                                                                                                                                                                                                         |
| Changes to the PCH Quality Reporting Program                                                                                                      | Across 11 PCHs, we estimated that our changes for the PCH Quality Reporting Program will result in a decrease of 84 hours and \$4,975 to the information collection burden for the FY 2028 program year and subsequent years.                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Changes to the LTCH QRP                                                                                                                           | Across 318 LTCHs, we estimated that our proposed changes for the LTCH QRP would result in a total information collection burden decrease of 4,473 hours associated with our policies and updated burden estimates and a total cost decrease of approximately \$207,309.29 for the FY 2028 LTCH QRP.                                                                                                                                                                                                                                                                                                                                             |
| Changes to the Medicare Promoting Interoperability Program                                                                                        | Across 4,550 eligible hospitals and CAHs, we estimated that our changes for the Medicare Promoting Interoperability Program result in a total information collection burden increase of 3,886 hours and \$213,962 for the EHR reporting period in CY 2026 and subsequent years.                                                                                                                                                                                                                                                                                                                                                                 |
| Transforming Episode Accountability Model (TEAM)                                                                                                  | We estimate for the TEAM proposals included in this proposed rule that there would be no significant change from the savings estimate in the FY 2026 IPPS/LTCH PPS final rule.                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| CJR-X                                                                                                                                             | We estimate that the proposed CJR-X model in this proposed rule would result in saving the Medicare program \$725 million across 5 performance years. We note these estimates represent only a portion of the potential savings CJR-X may generate, as the model does not have a specified end date.                                                                                                                                                                                                                                                                                                                                            |

## BILLING CODE 4120-01-C

*B. Background Summary***1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)**

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these “subsection (d) hospitals.” Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment (COLA) factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for an additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments.

In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments and, beginning in FY 2023 for IHS and Tribal hospitals and hospitals located in Puerto Rico, the new supplemental payment.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

With the recent enactment of section 6202 of the Consolidated Appropriations Act (CAA), 2026 (Pub. L. 119-75), under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through December 31, 2026. For discharges occurring on or after October 1, 2007, but before January 1, 2027, an MDH receives the higher of the Federal

rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). As section 6202 of the CAA, 2026 extended the MDH program through December 31, 2026, beginning on January 1, 2027, the MDH program will no longer be in effect absent a change in law. Because the MDH program is not authorized by statute beyond December 31, 2026, beginning January 1, 2027, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs. The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

**2. Hospitals and Hospital Units Excluded From the IPPS**

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); Inpatient psychiatric hospitals (IPF) and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the



U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable-cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

### 3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under

the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

### 4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

### 5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413. Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved GME program receive an additional payment for each Medicare discharge to reflect the higher patient care costs of teaching hospitals relative to non-teaching hospitals. The additional payment is based on the indirect medical education (IME) adjustment factor, which is calculated using a hospital's ratio of residents to beds and a multiplier, which is set by Congress. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. The regulations regarding the indirect medical education (IME) adjustment are located at 42 CFR 412.105.

### C. Summary of Provisions of Recent Legislation That Are Implemented in This Proposed Rule—Consolidated Appropriations Act, 2026 (Pub. L. 119–75)

Section 6201 of the Consolidated Appropriations Act (CAA), 2026 extended through the portion of FY 2027 occurring on October 1, 2026, through December 31, 2026, the modified definition of a low-volume

hospital and the methodology for calculating the payment adjustment for low-volume hospitals that had been in effect for FYs 2019 through 2025. Specifically, under section 1886(d)(12)(C)(i) of the Act, as amended, for FYs 2019 through 2026 and the portion of FY 2027 occurring on October 1, 2026 through December 31, 2026, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Under section 1886(d)(12)(D) of the Act, as amended, for discharges occurring in FYs 2019 through December 31, 2026, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year.

Section 6202 of the CAA, 2026 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program through the first quarter of FY 2027 (that is, through December 31, 2026).

### D. Summary of the Proposed Provisions

In this proposed rule, we set forth proposed payment and policy changes to the Medicare IPPS for FY 2027 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2027.

The following is a general summary of the changes that we are proposing to make:

#### 1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we included the following:

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2027.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the proposed FY 2027 status of new technologies approved for add-on payments for FY 2026, a presentation of our evaluation and analysis of the FY 2027 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by



the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Public Law 108–173, obtained in a town hall meeting for applications not submitted under an alternative pathway) with proposals for certain FDA market authorized technologies, and a discussion of the proposed status of FY 2027 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.

- A proposal to repeal the alternative pathway for new technology add-on payment and OPPS device pass-through applications, and require all applicants for new technology add-on payments and OPPS device pass-through payments to demonstrate that they meet all eligibility requirements to receive add-on payments and/or pass-through payments (as discussed in section II.E.7. of the preamble of this proposed rule).

## 2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III of the preamble of the proposed rule, we proposed revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but are not limited to, the following:

- The proposed FY 2027 wage index update using wage data from cost reporting periods beginning in FY 2023.

- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for FY 2027 based on the 2022 Occupational Mix Survey.

- Proposed application of the rural, imputed and frontier State floors, and proposed transition for the discontinuation of the low wage index hospital policy.

- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.

- Proposed adjustment to the wage index for acute care hospitals for FY 2027 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.

- The proposed transition for the discontinuation of the low wage index hospital policy.

- Proposed labor-related share for applying the FY 2027 wage index.

## 3. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2027

In section IV. of the preamble of the proposed rule, we discuss the following:

- Proposed calculation of Factor 1 and Factor 2 of the uncompensated care payment methodology.

- Proposed methodology for determining Factor 3 of the uncompensated care payment for FY 2027, which is the same methodology that was used for FY 2026.

- Proposed methodology for determining the amount of interim uncompensated care payments, using the average of the most recent 3 years of discharge data.

## 4. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section V. of the preamble of the proposed rule, we discussed proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed inpatient hospital market basket update for FY 2027.

- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.

- Proposed conforming amendments to reflect the statutory extension of the temporary changes to the low-volume hospital payment adjustment through December 31, 2026.

- Proposed conforming amendments to reflect the statutory extension of the MDH program through December 31, 2026.

- Proposed requirements to prohibit unlawful discrimination by graduate medical education programs and nursing and allied health education programs.

- Proposed modifications to the criteria for identifying new residency programs for purposes of direct graduate medical education (GME) and indirect medical education (IME) payments; proposed clarifications of the methodology for calculating direct GME and IME payments following a teaching hospital merger; and a notice of closure of two teaching hospitals and opportunities to apply for available slots.

- Proposed nursing and allied health (NAH) education program Medicare Advantage (MA) add-on rates and direct GME MA percent reductions for CY 2024; and proposed changes to the regulations for determining net costs of approved NAH education programs and changes to the procedures for allocating indirect NAH costs.

- Proposed update to and revision to the payment adjustment for certain immunotherapy cases.

- Proposed changes to the requirements of the Hospital Readmissions Reduction Program—Updating the proposed estimate of the financial impacts for the FY 2027 Hospital Readmissions Reduction Program.

- Proposed changes to the requirements of the Hospital Value-Based Purchasing Program—Updating the proposed estimate of the financial impacts for the FY 2027 Hospital Value-Based Purchasing Program.

- Proposed changes to the requirements of the Hospital-Acquired Condition Reduction Program—Updating the proposed estimate of the financial impacts for the FY 2027 Hospital-Acquired Conditions Reduction Program.

- Discussion of and proposed changes relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2027.

## 5. Proposed FY 2027 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble of the proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2027.

## 6. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VIII. of the preamble of the proposed rule, we discuss the following:

- Proposed changes to payments to certain excluded hospitals for FY 2027.

- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

## 7. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of the proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2027.

## 8. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of the proposed rule, we addressed the following:

- Proposed changes to the requirements for the Hospital Inpatient Quality Reporting Program.

- Proposed changes to the requirements for the PCH Quality Reporting Program.

- Proposed changes to the requirements for the Long-Term Care Hospital Quality Reporting Program.
- Proposed changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

#### 9. Other Proposals and Comment Solicitations Included in the Proposed Rule

Section X.A. of the preamble of this proposed rule includes proposed changes to TEAM that would affect episodes, quality measure assessment, and pricing methodology. We are also soliciting comment on an ambulatory surgical center episode RFI and a voluntary hospitals with physician ownership RFI.

Section X.B. of the preamble of the proposed rule, includes a proposed revision to the provider-based location criteria regulations applicable to off-campus facilities or organizations (§ 413.65).

Section X.C. of the preamble of the proposed rule includes proposals for the CJR–X Model with policies affecting participation, episodes, quality measure and assessment, pricing methodology, model overlap, financial arrangements, waivers of Medicare Program requirements, data sharing, and APM options.

In section X.D. of the preamble of this proposed rule, we are proposing the following:

- To reconcile non-renal organ acquisition costs for independent organ procurement organizations (IOPOs) and histocompatibility laboratories (HCLs), and to require the Medicare Administrative Contractor to establish, adjust if necessary, and publish the IOPO non-renal standard acquisition charges (SACs) and the HCL testing rates.
- To change certain existing policy and proposing to codify certain longstanding Medicare reasonable cost reimbursement policies, applicable to all providers reimbursed for all or for some of their services on a reasonable cost basis.
- To clarify and codify cost allocation principles.
- To codify the discretionary Administrator review of CMS reviewing official determinations with respect to appeals under § 413.420(g) for IOPOs and HCLs.

#### 10. Other Provisions of the Proposed Rule

Section X.A. of the preamble of the proposed rule includes our discussion of the MedPAC Recommendations.

Section X.B. of the preamble of the proposed rule includes a descriptive listing of the public use files associated with the proposed rule.

Section XI. of the preamble of the proposed rule includes the collection of information requirements for entities based on our proposals.

#### 11. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum of this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2027 prospective payment rates for operating costs and capital-related costs for acute care hospitals, including cost-of-living adjustment (COLA) factors for IPPS hospitals located in Alaska and Hawaii. We propose to establish the threshold amounts for outlier cases. In addition, in section V. of the Addendum of the proposed rule, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2027 for certain hospitals excluded from the IPPS.

#### 12. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum of this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2027 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2027. We propose to establish the adjustments for the wage index, labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

#### 13. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, LTCHs, and other entities.

#### 14. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2027 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS

for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).

- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.

- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

#### 15. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2026 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2026 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at <https://www.medpac.gov>.

## II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights

### A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These

adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

#### *B. Adoption of the MS-DRGs and MS-DRG Reclassifications*

For information on the adoption of the MS-DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS-DRG system, including yearly reviews and changes to the MS-DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2026 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085; 83 FR 41158 through 41258; 84 FR 42058 through 42165; 85 FR 58445 through 58596; 86 FR 44795 through 44961; 87 FR 48800 through 48891; 88 FR 58654 through 58787; 89 FR 69000 through 69109; 90 FR 36549 through 36649, respectively).

For discussion regarding our previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48799 through 48800).

#### *C. Proposed Changes to Specific MS-DRG Classifications*

##### **1. Discussion of Changes to Coding System and Basis for Proposed FY 2027 MS-DRG Updates**

###### **a. International Classification of Diseases, 10th Revision (ICD-10)**

Providers use the International Classification of Diseases, 10th Revision (ICD-10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS-DRG system. The ICD-10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding, as well as the ICD-10-CM and ICD-10-PCS Official Guidelines for Coding and Reporting.

###### **b. Basis for Proposed FY 2027 MS-DRG Updates**

The deadline for interested parties to submit MS-DRG classification change requests for FY 2027 was October 20, 2025. All requests are submitted to CMS via Medicare Electronic Application Request Information System™ (MEARIS™), accessed at <https://mearis.cms.gov>. Specifically, as indicated on the MEARIS™ site, the MS-DRG classification change request process may be used for requests to create, modify, or delete MS-DRGs, change ICD-10-CM diagnosis code(s) severity level designations, change ICD-10-PCS procedure code(s) Operating Room (O.R.) designations, or to review the CC Exclusions List or the surgical hierarchy.

Within MEARIS™, we have built in several resources to support users, including a “Resources” section available at <https://mearis.cms.gov/public/resources> with technical support available under “Useful Links” at the bottom of the MEARIS™ site. Questions regarding the MEARIS™ system can be submitted to CMS using the form available under “Contact”, also at the bottom of the MEARIS™ site.

We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the request for MS-DRG classification changes to CMS. The aforementioned burden is subject to the Paperwork Reduction Act (PRA) of 1995 and approved under OMB control number 0938-1431 and has an expiration date of 01/31/2029.

As we have discussed in prior rulemaking, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD-10, some types of requested changes to the MS-DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change.

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36550), beginning with FY 2027 rulemaking we are no longer summarizing in the proposed and final rules those requests that are not able to be considered for the upcoming FY. As noted, requests that require more extensive analysis may include those involving multiple MS-DRGs, overlapping logic across multiple Major Diagnostic Categories (MDCs), special logic such as diagnosis codes combined with procedure codes, and/or complex logic including code clusters or multiple logic lists. In December 2025,

we informed requestors via MEARIS™ if their MS-DRG classification change request was not able to be considered with the FY 2027 rulemaking cycle.

Interested parties should submit any MS-DRG classification change requests, including any comments and suggestions for FY 2028 consideration by October 20, 2026 via MEARIS™ at: <https://mearis.cms.gov/public/home>. We will inform requestors via MEARIS™ if the MS-DRG classification change request is not able to be considered with the upcoming fiscal year rulemaking cycle.

As we did for the FY 2026 IPPS/LTCH PPS proposed rule, for this FY 2027 IPPS/LTCH PPS proposed rule we are providing a test version of the ICD-10 MS-DRG GROUPEER Software, Version 44, so that the public can better analyze and understand the impact of the proposals included in this FY 2027 IPPS/LTCH PPS proposed rule. We note that this test software reflects the proposed GROUPEER logic for FY 2027. Therefore, it includes the new diagnosis and procedure codes that are effective for FY 2027 as reflected in Table 6A.—New Diagnosis Codes—FY 2027 and Table 6B.—New Procedure Codes—FY 2027 associated with this FY 2027 IPPS/LTCH PPS proposed rule and does not include the diagnosis codes that are invalid beginning in FY 2027 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2027 and Table 6D.—Invalid Procedure Codes—FY 2027 associated with this FY 2027 IPPS/LTCH PPS proposed rule. These tables are not published in the Addendum to this FY 2027 IPPS/LTCH PPS proposed rule, but are available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> as described in section VI. of the Addendum to this FY 2027 IPPS/LTCH PPS proposed rule. Because the diagnosis and procedure codes no longer valid for FY 2027 are not reflected in the test software, we are making available a supplemental file in Table 6P.1a that includes the mapped Version 44 FY 2027 ICD-10-CM codes and the deleted Version 43 FY 2026 ICD-10-CM codes and Table 6P.1b that includes the mapped Version 44 FY 2027 ICD-10-PCS codes and the deleted Version 43.1 FY 2026 ICD-10-PCS codes that should be used for testing purposes with users’ available claims data. Therefore, users will have access to the test software allowing them to build case examples that reflect the proposals included in this FY 2027 IPPS/LTCH PPS proposed rule. In addition, users will be able to view the draft version of the ICD-10 MS-DRG

Definitions Manual, Version 44 that contains the documentation for proposed FY 2027 ICD–10 MS–DRG GROUPER Version 44 logic changes and will also be able to view a draft version of the Definitions of Medicare Code Edits (MCE) Manual to review any changes that will become effective October 1 for FY 2027. As a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, any further changes to the MCE will be reflected in the finalized Definitions of Medicare Code Edits (MCE) Manual, made available in association with the annual IPPS/LTCH PPS final rule. We are making available the draft FY 2027 ICD–10 MCE Version 44 Manual file on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>.

The MCE manual is comprised of two chapters: *Chapter 1: Edit code lists* provides a listing of each edit, an explanation of each edit, and as applicable, the diagnosis and/or procedure codes for each edit, and *Chapter 2: Code list changes* summarizes the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software. The public may submit any questions, comments, concerns, or recommendations regarding the MCE to the CMS mailbox at [MSDRGClassificationChange@cms.hhs.gov](mailto:MSDRGClassificationChange@cms.hhs.gov) for our review and consideration.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 44, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 44, the draft version of the Definitions of Medicare Code Edits Manual, Version 44, and the supplemental mapping files in Tables 6P.1a and 6P.1b of the FY 2026 and FY 2027 ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes are available at <https://www.cms.gov/Medicare/Medicare-Fee->

[for-Service-Payment/Acute InpatientPPS/MS-DRG-Classifications-and-Software](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software).

The following are the changes that we are proposing to the MS–DRGs for FY 2027. We are inviting public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in this FY 2027 IPPS/LTCH PPS proposed rule. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data and clinical appropriateness. In other cases, we are proposing to maintain the existing MS–DRG classifications based on our analysis of claims data and clinical appropriateness. For this FY 2027 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2025 update of the FY 2025 MedPAR file, which contains hospital bills received from October 1, 2024 through September 30, 2025. In our discussion of the proposed MS–DRG reclassification changes, we refer to these claims data as the “September 2025 update of the FY 2025 MedPAR file.”

In deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on clinical factors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are

consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. We stated we believed that applying these criteria to the NonCC subgroup would better reflect resource stratification as well as promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs. We noted that in our analysis of MS–DRG classification requests for FY 2021 that were received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58661), we continue to apply the criteria to create subgroups, including application of the NonCC subgroup criteria, in our annual analysis of MS–DRG classification requests, consistent with our approach since FY 2021 when we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. Accordingly, in our analysis of the MS–DRG classification requests for FY 2027 that we received by October 20, 2025, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the following table.

| Criteria Number                                                             | Three-Way Split<br>123<br>(MCC vs CC vs NonCC)                                                                                                  | Two-Way Split<br>1_23<br>MCC vs (CC+NonCC)                                 | Two-Way Split<br>12_3<br>(MCC+CC) vs NonCC                                 |
|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|----------------------------------------------------------------------------|
| 1. At least 500 cases in the MCC/CC/NonCC group                             | 500+ cases for MCC group; and<br>500+ cases for CC group; and<br>500+ cases for NonCC group                                                     | 500+ cases for MCC group; and<br>500+ cases for (CC+NonCC) group           | 500+ cases for (MCC+CC) group; and<br>500+ cases for NonCC group           |
| 2. At least 5% of the patients are in the MCC/CC/NonCC group                | 5%+ cases for MCC group; and<br>5%+ cases for CC group; and<br>5%+ cases for NonCC group                                                        | 5%+ cases for MCC group; and<br>5%+ cases for (CC+NonCC) group             | 5%+ cases for (MCC+CC) group; and<br>5%+ cases for NonCC group             |
| 3. There is at least a 20% difference in average cost between subgroups     | 20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group            | 20%+ difference in average cost between MCC group and (CC+NonCC) group     | 20%+ difference in average cost between (MCC+CC) group and NonCC group     |
| 4. There is at least a \$2,000 difference in average cost between subgroups | \$2,000+ difference in average cost between MCC group and CC group; and<br>\$2,000+ difference in average cost between CC group and NonCC group | \$2,000+ difference in average cost between MCC group and (CC+NonCC) group | \$2,000+ difference in average cost between (MCC+CC) group and NonCC group |
| 5. The R2 of the split groups is greater than or equal to 3                 | R2 ≥ 3.0 for the three-way split within the base MS-DRG                                                                                         | R2 ≥ 3.0 for the two-way 1_23 split within the base MS-DRG                 | R2 ≥ 3.0 for the two-way 12_3 split within the base MS-DRG                 |

In general, once the decision has been made to propose to make further modifications to the MS-DRGs as described previously, such as creating a new base MS-DRG, or in our evaluation of a specific MS-DRG classification request to split (or subdivide) an existing base MS-DRG into severity levels, all five criteria must be met for the base MS-DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS-DRG, we typically evaluate the most recent year of MedPAR claims data available. For example, we stated earlier that for this FY 2027 IPPS/LTCH PPS proposed rule, our MS-DRG analysis was based on ICD-10 claims data from the September 2025 update of the FY 2025 MedPAR file. However, in our evaluation of requests to split an existing base MS-DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we typically analyze the most recent two years of data. This analysis includes two years of MedPAR claims data to compare the data results from one year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS-DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS-DRG is warranted is to determine if all the criteria is satisfied for a three-way split. In applying the criteria for a three-way split, a base MS-DRG is initially subdivided into the three subgroups: MCC, CC, and NonCC. Each subgroup is then analyzed in relation to the other two subgroups using the volume (Criteria 1 and 2), average cost (Criteria 3 and 4), and reduction in variance (Criteria 5). If the criteria fail, the next step is to determine if the

criteria are satisfied for a two-way split. In applying the criteria for a two-way split, a base MS-DRG is initially subdivided into two subgroups: "with MCC" and "without MCC" (1\_23) or "with CC/MCC" and "without CC/MCC" (12\_3). Each subgroup is then analyzed in relation to the other using the volume (Criteria 1 and 2), average cost (Criteria 3 and 4), and reduction in variance (Criteria 5). If the criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS-DRG. If the three-way split fails on any one of the five criteria and all five criteria for both two-way splits (1\_23 and 12\_3) are met, we would apply the two-way split with the highest R2 value. We note that if the request to split (or subdivide) an existing base MS-DRG into severity levels specifies the request is for either one of the two-way splits (1\_23 or 12\_3), in response to the specific request, we will evaluate the criteria for both of the two-way splits; however, we do not also evaluate the criteria for a three-way split.

## 2. MDC 04 (Diseases and Disorders of the Respiratory System)

### a. Short-Term External Heart Assist Systems

For this FY 2027 IPPS/LTCH PPS proposed rule, we received a request to reassign cases reporting procedure codes describing the insertion of a short-term external heart assist device from MDC 04 MS-DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) to MDC 05 (Diseases and Disorders of the Circulatory System) MS-DRG 215 (Other Heart Assist System Implant). According to the requestor, when patients are admitted with pulmonary conditions, such as pulmonary embolism, and have

Impella® Ventricular Support Systems inserted for cardiac support during a thrombectomy procedure, MS-DRGs 163, 164, or 165 are assigned. The requestor stated that cases reporting procedure codes describing the insertion of Impella® Ventricular Support Systems that are assigned to MS-DRGs 163, 164, or 165 require resources similar to cases that are assigned to MS-DRG 215. The requestor further requested that if CMS does not reassign cases reporting procedure codes describing the insertion of a short-term external heart assist device to MS-DRG 215, in the alternative, CMS should consider creating new MS-DRGs for cases reporting procedure codes describing the insertion of a short-term external heart assist device and major chest procedures.

In reviewing this request, we note that acute massive pulmonary embolism can lead to right ventricular (RV) failure and cardiogenic shock, requiring urgent treatment. Thrombolytic therapy is the standard treatment for high-risk pulmonary embolism in hemodynamically unstable patients. However, in cases where thrombolytics are contraindicated or ineffective, mechanical circulatory support can serve as a rescue therapy. While extracorporeal membrane oxygenation (ECMO) is commonly utilized, Impella® Ventricular Support Systems can offer right ventricular support in patients with pulmonary embolism-induced cardiogenic shock.<sup>1</sup> Impella® Ventricular Support Systems are

<sup>1</sup> Pandey, Asim MBBS<sup>a,\*</sup>; Parajuli, Samridhi MBBS<sup>b</sup>; Khanal, Prajwal MBBS<sup>c</sup>; Khanal, Kunjan MBBS<sup>d</sup>; Yadav, Ramsinhasan Prasad MBBS<sup>e</sup>. Hemodynamic improvement with Impella RP in acute massive pulmonary embolism: a narrative review of cardiovascular outcomes and pulmonary catheter pressure assessment. *Annals of Medicine & Surgery* 87(7):p 4303–4309, July 2025. | DOI: 10.1097/MS9.0000000000003431.

temporary heart assist devices intended to provide mechanical circulatory support by temporarily assisting the pumping function of the heart to provide adequate circulation of blood to critical organs while also allowing damaged heart muscle the opportunity to rest and recover in patients who need short-term support.

The requestor identified cases reporting procedure codes describing

the insertion of a short-term external heart assist device as reporting ICD-10-PCS codes 02HA3RZ (Insertion of short-term external heart assist system into the heart, percutaneous approach) and 5A0221D (Assistance with cardiac output using impeller pump, continuous). While we agree with the requestor that procedure code 02HA3RZ describes the insertion of a short-term external heart assist device, we note that

there are additional ICD-10-PCS codes in the classification that also describe the insertion of a short-term external heart assist device. Therefore, in reviewing this request, we identified the five additional ICD-10-PCS procedure codes that also describe the insertion of a short-term external heart assist device listed in the following table and included these codes in our analysis.

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| ICD-10-PCS Code | Description                                                                                                     |
|-----------------|-----------------------------------------------------------------------------------------------------------------|
| 02HA0RS         | Insertion of biventricular short-term external heart assist system into heart, open approach                    |
| 02HA0RZ         | Insertion of short-term external heart assist system into heart, open approach                                  |
| 02HA3RS         | Insertion of biventricular short-term external heart assist system into heart, percutaneous approach            |
| 02HA4RS         | Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach |
| 02HA4RZ         | Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach               |

To begin our analysis, we examined claims data from the September 2025 update of the FY 2025 MedPAR file for MS-DRGs 163, 164, and 165 to identify cases reporting ICD-10-PCS codes 02HA0RS, 02HA0RZ, 02HA3RS, 02HA3RZ, 02HA4RS, or 02HA4RZ. We agree with the requestor that when a

patient is admitted and has an Impella® external heart assist device inserted, two ICD-10-PCS codes are assigned: a code that describes the insertion of the short-term external heart assist device and code 5A0221D that describes assistance with an impeller pump. Because the assistance with an Impella® is always

coded with ICD-10-PCS code 5A0221D, we did not include this code in our analysis as the presence of the code would be expected to be identified in all cases. Our findings are shown in the following table.

| MS-DRG |                                                                       | Number of Cases | Average Length of Stay | Average Costs |
|--------|-----------------------------------------------------------------------|-----------------|------------------------|---------------|
| 163    | All cases                                                             | 13,396          | 8.2                    | \$40,641      |
|        | Cases reporting insertion of short-term external heart assist devices | 17              | 8.4                    | \$81,960      |
| 164    | All cases                                                             | 14,384          | 4                      | \$23,393      |
|        | Cases reporting insertion of short-term external heart assist devices | 0               | 0                      | \$0           |
| 165    | All cases                                                             | 6,431           | 2.3                    | \$17,981      |
|        | Cases reporting insertion of short-term external heart assist devices | 0               | 0                      | \$0           |

As shown in the table, we identified a total of 13,396 cases within MS-DRG 163 with an average length of stay of 8.2 days and average costs of \$40,641. Of these 13,396 cases, there were 17 cases that reported a procedure code describing the insertion of a short-term external heart assist device with an average length of stay of 8.4 days and average costs of \$81,960. There were zero cases reporting a procedure code describing the insertion of a short-term external heart assist device in MS-DRGs 164 and 165. The data analysis shows that for the cases in MS-DRG 163 reporting a procedure code describing the insertion of a short-term external heart assist device, the average length of stay is longer, and the average costs are

higher when compared to all cases in that MS-DRG.

To further review the consumption of hospital resources for cases reporting a procedure code describing the insertion of a short-term external heart assist device with a principal diagnosis of a pulmonary condition, we reviewed the claims data to identify cases reporting ICD-10-PCS codes 02HA0RS, 02HA0RZ, 02HA3RS, 02HA3RZ, 02HA4RS, or 02HA4RZ in other MS-DRGs in MDC 04 (Diseases and Disorders of the Respiratory System), specifically MS-DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and MS-DRG 173 (Ultrasound Accelerated and Other Thrombolysis with Principal

Diagnosis Pulmonary Embolism). We refer the reader to the ICD-10 MS-DRG Definitions Manual Version 43.1 (available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>) for complete listing of the MS-DRGs in MDC 04. There were zero cases reporting a procedure code describing the insertion of a short-term external heart assist device with a principal diagnosis of a pulmonary condition in MS-DRGs 166, 167, 168 or MS-DRG 173.

We then reviewed the claims data to further identify the principal diagnoses that were reported to determine what factors may also be contributing to the

higher average costs for the subset of cases that reported a procedure code describing the insertion of a short-term external heart assist device in MS-DRG

163. Our findings for the principal diagnoses that were reported within the claims data from the September 2025 update of the FY 2025 MedPAR file for

this subset of cases are shown in the following table:

| <b>DIAGNOSES REPORTED WITH A PROCEDURE CODE DESCRIBING THE INSERTION OF A SHORT-TERM EXTERNAL HEART ASSIST DEVICE IN MS-DRG 163</b> |                                                                |                                 |                               |                      |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|---------------------------------|-------------------------------|----------------------|
| <b>ICD-10-CM Code</b>                                                                                                               | <b>Description</b>                                             | <b>Number of Times Reported</b> | <b>Average Length of Stay</b> | <b>Average Costs</b> |
| 126.02                                                                                                                              | Saddle embolus of pulmonary artery with acute cor pulmonale    | 3                               | 7.3                           | \$61,956             |
| 126.09                                                                                                                              | Other pulmonary embolism with acute cor pulmonale              | 9                               | 7.6                           | \$79,521             |
| 126.92                                                                                                                              | Saddle embolus of pulmonary artery without acute cor pulmonale | 2                               | 11.5                          | \$111,452            |
| 126.99                                                                                                                              | Other pulmonary embolism without acute cor pulmonale           | 3                               | 9.7                           | \$89,619             |
| <b>Total</b>                                                                                                                        |                                                                | <b>17</b>                       | <b>8.4</b>                    | <b>\$ 81,960</b>     |

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As reflected in the table, all 17 cases reported a principal diagnosis of pulmonary embolism. While the results of the claims analysis as previously summarized indicate that the average costs of cases that reported a procedure code describing the insertion of a short-term external heart assist device are higher compared to the average costs for all cases in MS-DRG 163, we cannot ascertain from the claims data the additional resource use specifically attributable to the insertion of the short-term external heart assist device during the hospital stay as compared to the severity of illness of the patient and other circumstances of the admission. These data show that while cases that reported a procedure code describing the insertion of a short-term external heart assist device and a principal diagnosis of pulmonary embolism required greater resource utilization, there is a wide variance in average costs and average length of stay depending on the ICD-10-CM code reported as principal diagnosis. For example, the three cases that reported a principal diagnosis of I26.02 (Saddle embolus of pulmonary artery with acute cor pulmonale) had an average length of stay of 7.3 days and average costs of \$61,956, while the two cases that reported a principal diagnosis of I26.92 (Saddle embolus of pulmonary artery

without acute cor pulmonale) had an average length of stay of 11.5 days and average costs of \$111,452. When reviewing consumption of hospital resources for this subset of cases, it is unclear to what degree the higher average costs for these cases are attributable to the severity of illness of the patient and other circumstances of the admission as opposed to the insertion of a short-term external heart assist device. There may have been other factors contributing to the higher costs.

During our review of this issue and the examination of the cases reporting procedure codes describing the insertion of a short-term external heart assist device found in MS-DRG 163, as noted previously, we found these cases all reported principal diagnosis of pulmonary embolism. The ICD-10-codes that describe pulmonary embolism are currently assigned to MDC 04 (Diseases and Disorders of the Respiratory System). The diagnoses assigned to MDC 04 reflect conditions associated with the respiratory system. In ICD-10 the body or organ system is the axis of the classification, and diagnosis codes are classified by the body or organ system affected. The concept of clinical coherence generally requires that the patient characteristics included in the definition of each MS-DRG relate to a common organ system

or etiology and that a specific medical specialty should typically provide care to the patients in the DRG. These diagnosis codes would require reassignment to MDC 05 (Diseases and Disorders of the Circulatory System) to group to MDC 05 MS-DRG 215.

Although MDC 04 diagnoses such as pulmonary embolism can lead to RV failure and cardiogenic shock, which might be reasonable indications for the insertion of a short-term external heart assist device, it would not be appropriate to move these diagnoses into MDC 05 because it could inadvertently cause cases reporting these same MDC 04 diagnoses with a respiratory system procedure to be assigned to an “unrelated” MS-DRG because whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in a MS-DRG assignment to a surgical class referred to as “unrelated operating room procedures”.

To further examine the impact of moving the diagnosis codes describing pulmonary embolism into MDC 05, we analyzed claims data for cases reporting a respiratory system O.R. procedure and a principal diagnosis of pulmonary embolism. Our findings are reflected in the following table.

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| <b>CASES REPORTING A RESPIRATORY SYSTEM O.R. PROCEDURE WITH A PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM</b> |                                                                                           |                        |                               |                      |
|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|------------------------|-------------------------------|----------------------|
| <b>MS-DRG</b>                                                                                               | <b>Description</b>                                                                        | <b>Number of Cases</b> | <b>Average Length of Stay</b> | <b>Average Costs</b> |
| 163                                                                                                         | Major Chest Procedures with MCC                                                           | 5,470                  | 5.2                           | \$36,565             |
| 164                                                                                                         | Major Chest Procedures with CC                                                            | 1,750                  | 3.2                           | \$28,565             |
| 165                                                                                                         | Major Chest Procedures without CC/MCC                                                     | 186                    | 2.3                           | \$24,097             |
| 166                                                                                                         | Other Respiratory System O.R. Procedures with MCC                                         | 223                    | 10.6                          | \$33,791             |
| 167                                                                                                         | Other Respiratory System O.R. Procedures with CC                                          | 50                     | 6.1                           | \$20,171             |
| 168                                                                                                         | Other Respiratory System O.R. Procedures without CC/MCC                                   | 2                      | 2.5                           | \$9,592              |
| 173                                                                                                         | Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism | 971                    | 4.5                           | \$27,571             |
| <b>Total Cases</b>                                                                                          |                                                                                           | <b>8,652</b>           | <b>4.8</b>                    | <b>\$33,497</b>      |



As shown in the table, we identified 8,652 cases reporting a respiratory system O.R. procedure and a principal diagnosis of pulmonary embolism. If we were to move the diagnosis codes describing pulmonary embolism to MDC 05, these cases would be assigned to the surgical class referred to as “unrelated operating room procedures” as an unintended consequence because the surgical procedure reported on the claim would be considered unrelated to the MDC to which the case was assigned

based on the principal diagnosis. The data also indicates that there were more cases that reported an O.R. procedure assigned to MDC 04 with a principal diagnosis describing pulmonary embolism than there were cases that reported a procedure code describing the insertion of a short-term external heart assist device, and a principal diagnosis of pulmonary embolism in MDC 04 (8,652 cases versus 17 cases) demonstrating that inpatient admissions for pulmonary embolism more typically

have an O.R. procedure assigned to MDC 04 performed and do not report a procedure code describing the insertion of a short-term external heart assist device.

We also reviewed the cases reporting an O.R. procedure assigned to MDC 04 and a principal diagnosis describing pulmonary embolism to identify the top ten O.R. procedures assigned to MDC 04 that were reported within the claims data for these cases. Our findings are shown in the following table:

| <b>TOP 10 PROCEDURES ASSIGNED TO MDC 04 REPORTED WITH A PRINCIPAL DIAGNOSIS DESCRIBING PULMONARY EMBOLISM</b> |                                                                                                                                   |                                 |                               |                      |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------|----------------------|
| <b>ICD-10-PCS Code</b>                                                                                        | <b>Description</b>                                                                                                                | <b>Number of Times Reported</b> | <b>Average Length of Stay</b> | <b>Average Costs</b> |
| 02CQ3ZZ                                                                                                       | Extirpation of matter from right pulmonary artery, percutaneous approach                                                          | 3,887                           | 4.7                           | \$ 34,738            |
| 02CR3ZZ                                                                                                       | Extirpation of matter from left pulmonary artery, percutaneous approach                                                           | 2,314                           | 4.3                           | \$ 32,792            |
| X2CY3T7                                                                                                       | Extirpation of matter from great vessel using computer-aided mechanical aspiration, percutaneous approach, new technology group 7 | 519                             | 4.4                           | \$ 33,033            |
| 02FQ3Z0                                                                                                       | Fragmentation of right pulmonary artery, percutaneous approach, ultrasonic                                                        | 509                             | 4.7                           | \$ 28,313            |
| 02CP3ZZ                                                                                                       | Extirpation of matter from pulmonary trunk, percutaneous approach                                                                 | 492                             | 4.6                           | \$ 35,816            |
| 02FR3Z0                                                                                                       | Fragmentation of left pulmonary artery, percutaneous approach, ultrasonic                                                         | 378                             | 4.2                           | \$ 27,023            |
| 0JH60WZ                                                                                                       | Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, open approach                  | 77                              | 7.5                           | \$ 24,055            |
| 02FP3Z0                                                                                                       | Fragmentation of pulmonary trunk, percutaneous approach, ultrasonic                                                               | 31                              | 5.1                           | \$ 21,186            |
| 02FQ3ZZ                                                                                                       | Fragmentation of right pulmonary artery, percutaneous approach                                                                    | 27                              | 5.2                           | \$ 30,877            |
| 02CQ0ZZ                                                                                                       | Extirpation of matter from right pulmonary artery, open approach                                                                  | 21                              | 9.5                           | \$ 60,650            |

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As noted previously, if we were to move the diagnosis codes describing pulmonary embolism to MDC 05, cases reporting one of the O.R. procedures assigned to MDC 04 shown in the table would be assigned to the surgical class referred to as “unrelated operating room procedures” as an unintended consequence. Based on the results of our analysis, we believe that the diagnosis codes describing pulmonary embolism are most clinically aligned with the other diagnosis codes assigned to MDC 04 (where they are currently assigned). Considering the impact that moving the diagnoses describing pulmonary embolism to MDC 05 from MDC 04 would have, we also believe it would not be appropriate to move these diagnoses into MDC 05 because it would inadvertently cause cases reporting pulmonary embolism with O.R. procedures assigned to MDC 04 to be assigned to an unrelated MS-DRG.

We then explored alternative options, as was requested. We noted that the 17 cases reporting a procedure code describing the insertion of a short-term external heart assist device had an average length of stay of 8.4 days and average costs of \$81,960, as compared to the 13,396 cases in MS-DRG 163 that had an average length of stay of 8.2 days and average costs of \$40,641. While these cases reporting a procedure code describing the insertion of a short-term external heart assist device had average costs that were \$41,319 higher than the average costs of all cases in MS-DRG 163 (the highest severity level “with MCC” MS-DRG), there were only a total of 17 cases. The results of the claims analysis demonstrate that there is not sufficient claims data in the MedPAR file on which to assess the resource use of cases reporting a procedure code describing the insertion of a short-term external heart assist device with a

principal diagnosis from MDC 04 to consider the creation of a new MS-DRG. As noted previously, we cannot ascertain from the claims data the resource use specifically attributable to the insertion of a short-term external heart assist device during the hospital stay. Accordingly, we do not believe that the small subset of cases reporting a procedure code describing the insertion of a short-term external heart assist device with a principal diagnosis from MDC 04 warrants the creation of a new MS-DRG for these cases at this time.

Lastly, we explored reassigning cases reporting a procedure code describing the insertion of a short-term external heart assist device with an O.R. procedure assigned to MDC 04 and a principal diagnosis from MDC 04 to other MS-DRGs within MDC 04. However, our review did not support reassignment of these cases to any other

surgical MS-DRGs in MDC 04, as MS-DRGs 163, 164 and 165, where the cases are currently assigned, represent the highest surgical class in the surgical hierarchy of MDC 04. The surgical hierarchy is an ordering of surgical classes from most resource-intensive to least resource-intensive. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS-DRG associated with the most resource-intensive surgical class. We note that discussion of the surgical hierarchy is in section II.C.14. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule.

While the data analysis reflects that cases that report a procedure code describing the insertion of a short-term external heart assist device with an O.R. procedure assigned to MDC 04 and a principal diagnosis from MDC 04 demonstrate higher average costs in their respective MS-DRGs, as discussed in prior rulemaking (86 FR 44878), the MS-DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We further note that section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs. We will continue to evaluate the clinical coherence and resource consumption costs that impact this subset of cases and their current MS-DRG assignment.

Therefore, for the reasons stated previously, we are not proposing to reassign cases reporting procedure codes describing the insertion of a short-term external heart assist device from MDC 04 MS-DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) to MDC 05 MS-DRG 215 (Other Heart Assist System Implant) for FY 2027.

b. Fluorescence Guided Procedures of the Trunk Region Using Pafolacianine

CYTALUX® (pafolacianine) is a folate receptor-targeted fluorescent optical imaging agent used as an adjunct for the identification of malignant and non-malignant pulmonary lesions in adult patients with known or suspected lung cancer. CYTALUX® binds to the folate receptors on these cancer cells and is endocytosed into folate receptor positive cancer cells. CYTALUX® is administered intravenously prior to thoracic resection procedures and requires use of a near-infrared imaging (NIR) system to illuminate, thereby making cancer visible within the surgical field. CYTALUX® received FDA approval and is indicated as an adjunct for intraoperative identification of malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung. We note that CYTALUX® for the lung indication was approved for new technology add-on payments for FY 2024 (88 FR 58810 through 58818), FY 2025 (89 FR 69120 through 69126), and FY 2026 (90 FR 36668). We refer readers to section II.E.5 of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule for a discussion regarding the proposed FY 2027 status of technologies approved for FY 2026 new technology add-on payments, including CYTALUX® for the lung indication.

We received a request from the manufacturer of CYTALUX® to modify the Grouper logic of MS-DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with an ICD-10-PCS code that describes fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication that currently map to the lower severity level MS-DRG 165 (without CC/MCC) to the higher severity level MS-DRG 163 (with MCC) or MS-DRG 164 (with CC). According to the requestor, the utilization of CYTALUX® does not change the surgical procedure but adds significant value and cost to the procedure by improving the surgeon's ability to identify and completely resect malignant tissue. The

requestor performed their own analysis of Medicare claims data from 10/1/2023–3/31/2025 and stated they found approximately 135 cases that used CYTALUX® in thoracic resections and that they expect adoption to accelerate as NIR systems become more widely available. Additionally, the requestor stated they found 35% of the cases using CYTALUX® within MS-DRG 165, and the average costs of these cases exceeded the average costs of cases that did not report the usage of CYTALUX®. When controlling for procedural and facility variation, the requestor stated they found that CYTALUX cases in MS-DRG 165 were \$1,515 (8%) higher in cost and that 60% of the cases using CYTALUX® in MS-DRG 165 received new technology add-on payments averaging approximately \$2,300. The requestor further asserted that their review of the Inpatient Standard Analytical Files (SAF) indicated underreporting of CYTALUX® costs due to unclear inpatient drug billing guidance. The requestor stated they found that 64% of cases reporting an ICD-10-PCS code that describes fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication fall into MS-DRGs 163 or 164. Additionally, the requestor stated while they found that the average length of stay for cases reporting CYTALUX® in MS-DRG 165 is lower (1.9 vs. 2.3 days), the cost profile of these cases aligns more closely with the higher-severity MS-DRGs 164 and 163. According to the requestor, this misalignment leads to underpayment when CYTALUX® cases are grouped into MS-DRG 165, therefore CMS should reassign cases with an ICD-10-PCS code that describes fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication from MS-DRG 165 to MS-DRGs 163 or 164 to prevent barriers to hospital adoption of CYTALUX® as NIR system availability expands nationwide.

The following ICD-10-PCS procedure codes describe fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication.

**BILLING CODE 4120-01-P**

| ICD-10-PCS Code | Description                                                                                                     |
|-----------------|-----------------------------------------------------------------------------------------------------------------|
| 8E0W0EN         | Fluorescence guided procedure of trunk region using pafolacianine, open approach                                |
| 8E0W3EN         | Fluorescence guided procedure of trunk region using pafolacianine, percutaneous approach                        |
| 8E0W4EN         | Fluorescence guided procedure of trunk region using pafolacianine, percutaneous endoscopic approach             |
| 8E0W7EN         | Fluorescence guided procedure of trunk region using pafolacianine, via natural or artificial opening            |
| 8E0W8EN         | Fluorescence guided procedure of trunk region using pafolacianine, via natural or artificial opening endoscopic |

In the ICD-10 MS-DRGs Definitions Manual Version 43.1, procedure codes 8E0W0EN, 8E0W3EN, 8E0W4EN, 8E0W7EN and 8E0W8EN are designated as non-O.R. procedures for purposes of MS-DRG assignment, therefore when CYTALUX® is utilized during a

procedure for the lung indication, the ICD-10-PCS code describing the surgical procedure will determine the surgical MS-DRG assignment based on the principal diagnosis reported.

We examined claims data from the September 2025 update of the FY 2025

MedPAR file for MS-DRGs 163, 164, and 165 to identify cases reporting one of the five procedure codes listed previously that describe fluorescence guided surgery using CYTALUX® (pafolacianine). Our findings are shown in the following table:

| MS-DRGS 163 – 165: ALL CASES AND CASES REPORTING PROCEDURE CODES THAT DESCRIBE FLUORESCENCE GUIDED SURGERY USING CYTALUX® (PAFOLACIANINE) |                                                                                                     |                 |                        |               |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|-----------------|------------------------|---------------|
| MS-DRG                                                                                                                                    |                                                                                                     | Number of Cases | Average Length of Stay | Average Costs |
| 163                                                                                                                                       | All cases                                                                                           | 13,396          | 8.2                    | \$40,641      |
|                                                                                                                                           | Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) | 14              | 4.6                    | \$30,818      |
| 164                                                                                                                                       | All cases                                                                                           | 14,384          | 4                      | \$23,393      |
|                                                                                                                                           | Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) | 87              | 2.7                    | \$22,426      |
| 165                                                                                                                                       | All Cases                                                                                           | 6,431           | 2.3                    | \$17,981      |
|                                                                                                                                           | Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) | 58              | 1.9                    | \$20,854      |

#### BILLING CODE 4120-01-C

As shown in the table, in MS-DRG 163, we identified a total of 13,396 cases with an average length of stay of 8.2 days and average costs of \$40,641. Of those 13,396 cases, there were 14 cases reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with average costs lower than the average costs in the FY 2025 MedPAR file for MS-DRG 163 (\$30,818 compared to \$40,641) and a shorter average length of stay (4.6 days compared to 8.2 days). In MS-DRG 164, we identified a total of 14,384 cases with an average length of stay of 4 days and average costs of \$23,393. Of those 14,384 cases, there were 87 cases reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with average costs lower than the average costs in the FY 2025 MedPAR file for MS-DRG 164 (\$22,426 compared to \$23,393) and a shorter average length of stay (2.7 days compared to 4 days). In MS-DRG 165, we identified a total of 6,431 cases with

an average length of stay of 2.3 days and average costs of \$17,981. Of those 6,431 cases, there were 58 cases reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with average costs higher than the average costs in the FY 2025 MedPAR file for MS-DRG 165 (\$20,854 compared to \$17,981), and a shorter average length of stay (1.9 days compared to 2.3 days).

The 58 cases in MS-DRG 165 reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), without a secondary diagnosis code designated as a CC or MCC, have a shorter average length of stay (1.9 days versus 4 days) and lower average costs (\$20,854 versus \$23,393) when compared to all the cases in MS-DRG 164. Similarly, the 58 cases in MS-DRG 165 reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) have a shorter average length of stay (1.9 days versus 8.2 days) and lower average costs (\$20,854 versus

\$40,641) when compared to all the cases in MS-DRG 163. While the data analysis reflects that cases that report one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), without a secondary diagnosis code designated as a CC or MCC, demonstrate slightly higher average costs compared to all the cases in MS-DRG 165, we believe these cases are more suitably grouped to MS-DRG 165, where they are currently assigned, based on the closer similarities in resource utilization compared to all the cases in their respective MS-DRG. As discussed in prior rulemaking (86 FR 44878), the MS-DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We further note that section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases

incurring extraordinarily high costs. Moreover, the data do not indicate cases reporting procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), without a secondary diagnosis code designated as a CC or MCC, utilize similar resources when compared to the cases assigned to MS-DRGs 163 and 164. We believe it would be advantageous to allow for more claims data to be analyzed in consideration of any future modifications to the MS-DRGs for which fluorescence guided surgeries using CYTALUX® (pafolacianine) are assigned. We will continue to evaluate the clinical coherence and resource consumption costs that impact this subset of cases and their MS-DRG assignment.

Therefore, for the reasons stated, for FY 2027, we are proposing to maintain the current structure of MS-DRGs 163, 164, and 165.

### 3. MDC 05 (Diseases and Disorders of the Circulatory System): WiSE® CRT System

The WiSE® CRT System is an implantable cardiac pacing system that delivers left ventricular endocardial pacing (LVEP) specifically for cardiac resynchronization therapy (CRT) without the use of wires or leads going into the heart. The WiSE® CRT System was designed to stimulate the endocardial surface of the left ventricle (LV) without a transvenous LV lead. Working in conjunction with previously implanted standard commercially available pacemakers or defibrillators, the WiSE® CRT System utilizes a wireless ultrasound-based energy transmission to a small, implanted electrode in the LV endocardium, which converts the ultrasound signal into pacing energy. According to the requestor, the WiSE® CRT System is engineered to benefit patients with heart failure who were previously untreatable with conventional CRT or who are considered at high risk for placement of a coronary sinus (CS) lead for CRT upgrades. The WiSE® CRT system consists of four components: the receiver, also known as the receiver electrode or electrode (implanted via catheter), delivery sheath, battery and transmitter. An external programmer is used to adjust parameters of the battery. The WiSE® CRT System was approved for new technology add-on payments for FY 2026 (90 FR 36821 through 36823). We refer readers to section II.E.4.a of the preamble of this proposed rule for a discussion regarding the proposed FY 2027 status of technologies approved for FY 2026 new technology add-on

payments, including the WiSE® CRT System.

In support of the new technology add-on payment application that was submitted for FY 2026 consideration, we received a request to create new ICD-10-PCS codes to differentiate cardiac procedures that involve the insertion of an implantable endocardial pacing system, such as the WiSE® CRT System, and a code proposal was displayed in association with the Spring 2025 ICD-10 Coordination and Maintenance Committee Update. As a result, effective October 1, 2025 (FY 2026), we implemented the following ICD-10-PCS procedure codes to identify the insertion of the WiSE® CRT System: X2HN37B (Insertion of endocardial pacing electrode into left ventricle, percutaneous approach, new technology group 11) in combination with XHH80HB (Insertion of ultrasound transmitter and battery for endocardial pacing electrode into chest subcutaneous tissue and fascia, open approach, new technology group 11). In the ICD-10 MS-DRGs Version 43.1, this procedure code combination is assigned to MS-DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, without MCC respectively) in a logic list referred to as “CARDIAC PACEMAKER DEVICE” that includes 720 other ICD-10-PCS procedure code combinations that identify the insertion of cardiac pacemakers. When reported as standalone procedures, ICD-10-PCS code X2HN37B is assigned to MDC 05 MS-DRGs 264 (Other Circulatory System O.R. Procedures) and ICD-10-PCS code XHH80HB is assigned to MDC 05 MS-DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with and without MCC, respectively). We refer the reader to the ICD-10 MS-DRG Definitions Manual Version 43.1, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software> for complete documentation of the GROUPE logic for MS-DRGs 242, 243, 244, 259, 259 and 264.

For this FY 2027 IPPS/LTCH PPS proposed rule, we received a request to reassign the ICD-10-PCS procedure codes that describe the insertion of the WiSE® CRT System from MS-DRGs 242, 243, and 244 to MS-DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively). The requestor stated that insertion of the WiSE® CRT System electrode, which is described by ICD-10-PCS code X2HN37B, is similar both clinically and in terms of resource utilization, to the

procedure codes that describe the insertion of leadless pacemakers that are currently assigned to MS-DRGs 228 and 229. The requestor further stated that the cases assigned to MS-DRGs 242, 243, and 244 involve traditional pacemaker devices with leads and are dissimilar to the WiSE® CRT System. According to the requestor, based on clinical function, implant methodology, and patient profile, the WiSE® CRT System more closely aligns with leadless pacemaker technology than with traditional pacemaker procedures as the use of multi-modality imaging, arterial navigation, and ultrasound-guided transmitter placement adds to both time and resource utilization, paralleling the procedural profile of leadless pacemaker implantation rather than traditional pacemaker surgery. Therefore, the requestor suggested that CMS reassign ICD-10-PCS code X2HN37B that describes the insertion of the electrode of the WiSE® CRT System to MS-DRGs 228 and 229 to appropriately group the procedure with the leadless pacemaker cases.

To begin our analysis, we reviewed the procedure codes. As noted previously, a code proposal was displayed as part of the ICD-10 Coordination and Maintenance Committee Spring 2025 update process to create unique ICD-10-PCS codes to describe the insertion of an implantable endocardial pacing system such as the WiSE® CRT System. As discussed in prior rulemaking (86 FR 44805), we used our established process to examine the MS-DRG assignment for the predecessor codes to determine the most appropriate MS-DRG assignment of new procedure codes X2HN37B and XHH80HB for FY 2026. Specifically, we review the predecessor code and MS-DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS-DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS-DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code.

Because the codes that describe the insertion of the WiSE® CRT System were effective October 1, 2025 (FY 2026), we would not expect the codes to be reported in the FY 2025 claims data used for this proposed rule. We examined claims data from the September 2025 update of the FY 2025

MedPAR file for MS-DRGs 242, 243, and 244 and confirmed that there were zero cases reporting the procedure codes describing the insertion of the WiSE® CRT System across MS-DRGs 242, 243, and 244.

We reviewed this issue and note the requestor is correct that the ICD-10-PCS codes that describe the insertion of intracardiac pacemakers, also known as “leadless” pacemakers, are currently assigned to MS-DRGs 228 and 229. In leadless pacemakers, the components are combined into a single device implanted within a heart chamber. They do not require a chest incision, a subcutaneous pocket or a tunneled lead. These devices are implanted via a femoral vein transcatheter approach and then advanced into the heart chamber, fixed to the chamber wall, and released. Conventional pacemakers are comprised of a metal generator (battery + electronics) placed under the skin in the upper chest, connected by one or more insulated wires (leads) threaded into the heart. We agree that leadless pacemakers and the WiSE® CRT System electrode are clinically coherent in that both eliminate the need for traditional, wire-based leads that run from the device to the heart muscle to transmit electrical impulses to the heart. We believe that the electrode of the WiSE® CRT System is more closely aligned

with the leadless pacemakers assigned to MS-DRGs 228 and 229 as compared to the insertion of conventional pacemakers assigned to MS-DRGs 242, 243, and 244. While our analysis did not identify any cases reporting the procedure code that describes the insertion of the electrode of the WiSE® CRT System, based on our review of the clinical issues, and recognizing that it is expected that some Medicare patients will receive the WiSE® CRT System on an inpatient basis, we believe reassigning ICD-10-PCS code X2HN37B that describes the insertion of the endocardiac pacing electrode into the left ventricle from MS-DRG 264 to MDC 05 MS-DRGs 228 and 229 would improve clinical coherence in these MS-DRGs.

For these reasons, for FY 2027, we are proposing to reassign procedure code X2HN37B (Insertion of endocardiac pacing electrode into left ventricle, percutaneous approach, new technology group 11) from MS-DRG 264 to MS-DRGs 228 and 229 for clinical coherence and to better account for the anticipated resources required. We are also proposing to delete the procedure code combination of X2HN37B and XHH80HB from the GROUPER logic of MS-DRGs 242, 243, and 244. Under this proposal, procedure code X2HN37B will not need to be reported as part of a

procedure code combination or procedure code “cluster” to satisfy the logic for assignment to MS-DRGs 228 and 229. When reported as a standalone procedure, ICD-10-PCS code XHH80HB (Insertion of ultrasound transmitter and battery for endocardiac pacing electrode into chest subcutaneous tissue and fascia, open approach, new technology group 11) will be assigned to proposed new MDC 05 MS-DRG 210 (Cardiac Pacemaker Revision or Device Replacement with MCC) and proposed new MS-DRG 211 (Cardiac Pacemaker Revision or Device Replacement without MCC), which are discussed later in this section.

Consistent with our annual review of the MS-DRGs, we consider changes in resource consumption, treatment patterns, technology, and any other factors that may change the relative use of hospital resources. In our review of the claims data from the September 2025 update of the FY 2025 MedPAR file for this request, we identified a low volume of cases for MS-DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with MCC and without MCC, respectively), where procedure code XHH80HB is assigned when reported as a standalone procedure in Version 43.1. Our findings are shown in the following table.

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| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|--------|-----------------|------------------------|---------------|
| 258    | 35              | 7                      | \$28,275      |
| 259    | 68              | 3.3                    | \$16,833      |

In light of the initial findings of only 35 cases for MS-DRG 258 and 68 cases in MS-DRG 259, we further reviewed the MedPAR claims data for cases

assigned to MS-DRGs 258 and 259 for the past 5 fiscal years. As reflected in the following tables, these data indicate that the number of cases grouping to

MS-DRGs 258 and 259 has generally declined.

| FY and MedPAR Data Reviewed for MS-DRG 258 | Number of Cases | Average Length of Stay | Average Costs |
|--------------------------------------------|-----------------|------------------------|---------------|
| FY 2023 (FY 2021 MedPAR)                   | 579             | 6.3                    | \$22,031      |
| FY 2024 (FY 2022 MedPAR)                   | 572             | 6.3                    | \$23,522      |
| FY 2025 (FY 2023 MedPAR)                   | 557             | 6.6                    | \$24,910      |
| FY 2026 (FY 2024 MedPAR)                   | 484             | 6.2                    | \$24,662      |
| FY 2027 (FY 2025 MedPAR)                   | 35              | 7                      | \$28,275      |

| FY and MedPAR Data Reviewed for MS-DRG 259 | Number of Cases | Average Length of Stay | Average Costs |
|--------------------------------------------|-----------------|------------------------|---------------|
| FY 2023 (FY 2021 MedPAR)                   | 652             | 3.1                    | \$16,695      |
| FY 2024 (FY 2022 MedPAR)                   | 693             | 3                      | \$16,520      |
| FY 2025 (FY 2023 MedPAR)                   | 696             | 3                      | \$15,912      |
| FY 2026 (FY 2024 MedPAR)                   | 692             | 3                      | \$16,546      |
| FY 2027 (FY 2025 MedPAR)                   | 68              | 3.3                    | \$16,833      |

We note that, if, during our annual MS-DRG analysis we identify that there are only a few patients in a respective MS-DRG, consistent with our established process in deciding whether to propose to make further modifications, we consider if there have been potential changes in the clinical characteristics of the patients, treatment patterns, or resource utilization. A principle of the MS-DRGs and the characteristics of a meaningful DRG classification scheme is the ability to detect such changes and accordingly, propose clinically appropriate modifications that are also consistent with resource utilization. We have noted in prior rulemaking that we prefer to have a substantial number of cases in an MS-DRG because having larger

clinically cohesive groups within an MS-DRG provides greater stability for annual updates to the relative payment weights. In light of these considerations, and the low volume of cases in MS-DRGs 258 and 259, we believed it was appropriate to further analyze how to potentially reclassify these cases.

Accordingly, using the September 2025 update of the FY 2025 MedPAR file, we examined whether there were other MS-DRGs to which these cases could appropriately be reassigned. We note that surgical MS-DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively) also include procedure codes related to cardiac pacemakers. A cardiac pacemaker device replacement

(generator change) is a procedure to change an old battery (generator) for a new one. A cardiac pacemaker revision is a procedure that may involve replacing, moving, or adding leads, or fixing the pocket of the generator. While the terms are distinct, both cardiac pacemaker revision and cardiac pacemaker replacement procedures are performed in order to improve the way the cardiac pacemaker system works.

As such, we reviewed the claims data from the September 2025 update of the FY 2025 MedPAR file for MS-DRGs 260, 261, and 262 to examine the resource utilization associated with cases assigned to these MS-DRGs. Our findings are shown in the following table.

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|--------|-----------------|------------------------|---------------|
| 260    | 2,730           | 7.5                    | \$29,313      |
| 261    | 2,847           | 3.5                    | \$17,151      |
| 262    | 795             | 2.5                    | \$15,119      |

As part of this analysis, we also reviewed the MS-DRGs for cases reporting ICD-10-PCS codes describing cardiac pacemaker device replacement procedures by severity claims data for

MS-DRG 259 because this MS-DRG includes cases reporting a CC as well as cases reporting a NonCC. Therefore, we analyzed the claims data to determine the number of cases, the average length

of stay, and average costs for the cases in MS-DRG 258 and 259 by severity level (1=MCC, 2=CC, and 3=NonCC). Our findings are shown in the following table.

| MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|--------|-----------------|------------------------|---------------|
| 258-1  | 35              | 7                      | \$28,275      |
| 259-2  | 42              | 4                      | \$18,246      |
| 259-3  | 26              | 2                      | \$14,552      |

As shown in the data, the 35 cases reporting an MCC in MS-DRG 258 have an average length of stay of 7 days with average costs of \$28,275, which is comparable to the cases in MS-DRG 260 reporting an MCC that have an average length of stay of 7.5 days with average costs of \$29,313. The 42 cases reporting a CC in MS-DRG 259 have an average length of stay of 4 days with average costs of \$18,246, which is comparable to the cases in MS-DRG 261 reporting an CC that have an average length of stay of 3.5 days with average costs of \$17,151. The 26 cases not reporting a CC or an MCC in MS-DRG 259 have an average length of stay of 2 days with average costs of \$14,552, which is comparable to the cases in MS-DRG 262 not reporting a CC or an MCC that have

an average length of stay of 2.5 days with average costs of \$15,119.

We reviewed these findings and believe that it may no longer be necessary to subdivide these MS-DRGs based on the cardiac pacemaker revision or device replacement procedure codes reported. We note that DRGs that differentiate cases reporting procedure codes describing cardiac pacemaker device replacement from cases reporting procedure codes describing cardiac pacemaker revisions have existed since 1983 (48 FR 39878) when Congress amended the Social Security Act to include a national DRG-based hospital prospective payment system for all Medicare patients.

Our analysis of claims data from the September 2025 update of the FY 2025 MedPAR file shows that in the 43 years

since the DRGs for cases reporting cardiac pacemaker revision procedures and cases reporting cardiac pacemaker device replacement procedures were created, the resource utilization appears to now be aligned, and the cases are clinically coherent, and therefore we believe it is appropriate to now restructure these MS-DRGs accordingly. Specifically, we believe it would be appropriate to delete MS-DRGs 258, 259, 260, 261, and 262, and to create new MS-DRGs for cases reporting ICD-10-PCS codes describing cardiac pacemaker revision or device replacement procedures, based on our analysis and review of the cases grouping to these MS-DRGs.

The following table illustrates our simulation of the proposal.

| Proposed New MS-DRG                                                      | Number of Cases | Average Length of Stay | Average Costs |
|--------------------------------------------------------------------------|-----------------|------------------------|---------------|
| Proposed new MS-DRG XXX Cardiac Pacemaker Revision or Device Replacement | 6,475           | 5.1                    | \$22,086      |

Consistent with our established process as discussed in section II.C.1.b. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, once the decision has been made to propose to make further modifications to the MS-DRGs, such as creating a new base MS-

DRG, all five criteria to create subgroups must be met for the base MS-DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS-DRG as discussed in section II.C.1.b. of the preamble of this FY 2027 IPPS/LTCH

PPS proposed rule. As shown, a three-way split of the proposed new MS-DRG failed to meet the criterion that there be at least a 20% difference in average costs between the CC and NonCC subgroup.

| Proposed New MS-DRGs | Number of Cases | Average Length of Stay | Average Costs |
|----------------------|-----------------|------------------------|---------------|
| With MCC             | 2,765           | 7.5                    | \$29,300      |
| With CC              | 2,889           | 3.5                    | \$17,167      |
| Without CC/MCC       | 821             | 2.5                    | \$15,101      |

As discussed in section II.C.1.b. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, if the criteria for a three-way split fail, the next step is to

determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the “with MCC” and “without MCC”

subgroups and found that all five criteria were met. The following table illustrates our findings.

| Proposed New MS-DRGs | Number of Cases | Average Length of Stay | Average Costs |
|----------------------|-----------------|------------------------|---------------|
| With MCC             | 2,765           | 7.5                    | \$29,300      |
| Without MCC          | 3,710           | 3.3                    | \$16,710      |

#### BILLING CODE 4120-01-C

For the proposed new MS-DRGs for cases reporting procedure codes describing cardiac pacemaker revision or device replacement, there is at least (1) 500 cases in the MCC group and 500 cases in the without MCC group; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC group; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a \$2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS-DRG in capturing differences in expected cost between the proposed MS-DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

Therefore, for FY 2027, we are proposing to delete MS-DRGs 258, 259, 260, 261, and 262 and to create two new MS-DRGs with a two-way severity level

split for cases reporting procedure codes describing cardiac pacemaker revision or device replacement in MDC 05. These proposed new MS-DRGs are proposed new MS-DRG 210 (Cardiac Pacemaker Revision or Device Replacement with MCC) and proposed new MS-DRG 211 (Cardiac Pacemaker Revision or Device Replacement without MCC). We refer the reader to Table 6P.2a associated with this FY 2027 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index>) for the list of procedure codes we are proposing to define in the logic for the proposed new MS-DRGs. We note that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule.

In our evaluation of this MS-DRG classification request, we also noted that we identified 7,772 cases in base MS-DRG 264 (Other Circulatory System O.R. Procedures) with an average length of

stay of 9.4 days and average costs of \$29,545. Accordingly, in connection with our analysis we applied the five criteria as described in section II.C.1.b. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule to determine if it would be appropriate to subdivide cases currently assigned to base MS-DRG 264 into severity levels. This analysis includes two years of MedPAR claims data to compare the data results from one year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also to validate that the established severity levels within a base MS-DRG are supported. Therefore, we reviewed the claims data for base MS-DRG 264 using the September 2024 update of the FY 2024 MedPAR file and the September 2025 update of the FY 2025 MedPAR file, which were used in our analysis of claims data for MS-DRG reclassification requests for FY 2026 and FY 2027, respectively. Our findings are shown in the following table:

| FY Data | Number of Cases | Number of Cases MCC | Number of Cases CC | Number of Cases Non CC | Average Costs No Split | Average Costs MCC | Average Costs CC | Average Costs Non CC | Average Costs MCC/CC combo | Average Costs CC/NonCC combo |
|---------|-----------------|---------------------|--------------------|------------------------|------------------------|-------------------|------------------|----------------------|----------------------------|------------------------------|
| 2024    | 7,762           | 5,276               | 2,332              | 154                    | \$29,236               | \$33,846          | \$19,720         | \$15,393             | \$29,516                   | \$19,452                     |
| 2025    | 7,772           | 5,255               | 2,372              | 145                    | \$29,545               | \$34,100          | \$20,251         | \$16,501             | \$29,793                   | \$20,035                     |

First, we applied the criteria to create subgroups for the three-way severity level split. We found that the criterion

that there be at least 5% of the patients are in each of the MCC, CC, and NonCC subgroups failed based on the data in

both the FY 2024 and FY 2025 MedPAR files. The criterion that there be at least 500 cases for each subgroup also was



not met, as shown in the table for both years. Specifically, for the “with MCC”, “with CC”, and “without CC/MCC” split, there were only 154 cases in the “without CC/MCC” subgroup based on the data in the FY 2024 MedPAR file and only 145 cases in the “without CC/MCC” subgroup based on the data in the FY 2025 MedPAR file.

As discussed in section II.C.1.b. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the “with MCC” and “without MCC” subgroups and found that all five criteria were met for both years. For both years, there are at least (1) 500 cases in the MCC group and 500 cases in the without MCC group; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC group; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a \$2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that a “with MCC” and “without MCC” severity level split increases the explanatory power of the base MS-DRG in capturing differences in expected cost between the MS-DRG severity level splits by at least 3 percent and thus improves the overall accuracy of the IPPS payment system.

As the claims data supports a two-way severity level split for cases reporting other circulatory system O.R. Procedures, for FY 2027, we are proposing to delete base MS-DRG 264 and proposing to create two new MS-DRGs with a two-way severity level split for cases reporting other circulatory system O.R. Procedures in MDC 05. These proposed new MS-DRGs are proposed new MS-DRG 361 (Other Circulatory System O.R. Procedures with MCC) and proposed new MS-DRG 362 (Other Circulatory System O.R. Procedures without MCC). Under this proposal, we would reassign the 1,447 listed procedure codes in the Grouper logic of MS-DRG 264 to new MS-DRGs 361 and 362. We refer the reader to the ICD-10 MS-DRG Version 43.1 Definitions Manual (which is available via the internet on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software>) for complete documentation of the Grouper logic for MS-DRG 264. We note that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the

preamble of this FY 2027 IPPS/LTCH PPS proposed rule.

#### 4. MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

##### a. Spinal Fusion and Pelvic Fixation Procedures

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18012 through 108013) and final rule (90 FR 36550 through 36552), we received a request to modify the Grouper logic of new MS-DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device), new MS-DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC), and new MS-DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC); new MS-DRG 447 (Multiple Level Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device) and new MS-DRG 448 (Multiple Level Spinal Fusion Except Cervical without MCC); and MS-DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with an ICD-10-PCS code that describes fusion of a sacroiliac joint using an internal fixation device with tulip connector or insertion of an internal fixation device with tulip connector into a pelvic bone with another spinal fusion procedure code that currently map to the lower severity level MS-DRG to the highest severity level (with MCC) MS-DRG.

In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36552), we noted that we would continue to consider the request in connection with future rulemaking. We stated that the logic for MS-DRGs 456, 457, and 458 is defined by extensive fusions, in addition to specific diagnosis code logic and that MS-DRGs 426, 427, 428, 447, and 448 had recently become effective October 1, 2024, which we were continuing to monitor. We also stated that the data analysis necessary to examine the intricate logic within the spinal fusion MS-DRGs outlined in the request is complex and would require additional time for careful consideration of case redistribution and potential relative weight impacts, in connection with other related spinal fusion procedure requests that may be discussed in future rulemaking.

For this FY 2027 IPPS/LTCH PPS proposed rule, we received another

request from the same manufacturer to reassign cases reporting the use of the iFuse Bedrock™ Granite Implant System (also referred to as tulip connector) in spinal fusion procedures that currently map to the lower severity level MS-DRG to the highest severity level (with MCC) MS-DRG for the previously listed MS-DRGs that were discussed in connection with the FY 2026 IPPS/LTCH PPS rulemaking; MS-DRGs 426, 427, 428, 447, 448, 456, 457, and 448.

The requestor stated that historically, the junction between the lumbar spine and the sacrum (the L5-S1 spinal level), has been the most challenging level in which to achieve fusion. One of the primary reasons is because of our upright posture and normal spinal curvature that causes the L5-S1 intervertebral disc to become significantly inclined (tilted forward). The requestor indicated that this results in significant shear load at this level, making this the level most likely to break down, and the level most challenging to stabilize during a fusion procedure. Per the requestor, the L5-S1 level is the junction between the mobile spine above and the much more rigid sacrum/pelvis below, leading to stress concentration at this level. The L5-S1 level experiences the most axial load as it is the base of the spine supporting the weight of the entire torso. Finally, the L5-S1 level experiences progressively more stress/load with more levels of the spine that are fused. The requestor stated that including additional levels in the fusion construct results in additional lengthening of the lever arm and increasing the loads acting at the L5-S1 level.

The requestor stated that anchorage of spinal instrumentation into the sacrum is also challenging. The sacrum is narrow in the posterior to anterior dimension, resulting in the need to place shorter screws. The pedicles are larger diameter which results in diminished cortical engagement of the screws. According to the requestor, the bone structure of the sacrum is also suboptimal for screw anchorage as the density of the sacrum is frequently diminished, particularly in older adults, and especially in those with osteoporosis. The requestor stated that the problem also exists for older adults without osteoporosis.

The requestor indicated that historically, surgeons added additional spinal instrumentation fixation anchor points into the pelvis (ilium and sacrum) to try and help solve the biomechanical and anatomic challenges previously described. These anchors (typically longer, larger diameter

pedicle-type screws) are placed into the ilium or placed crossing through the sacrum and then into the ilium. These screws are then connected to the spinal instrumentation and improve the biomechanical stability of the spinal instrumentation construct. The requestor stated that clinical practice has evolved to include pelvic fixation as an integral part of spinal instrumentation with multi-level fusions ending at the sacrum. The requestor stated that the current standard is to include pelvic fixation in fusions of four levels or more.<sup>2</sup> The requestor added that recently, recommendations have been suggested to include pelvic fixation in some instances if the fusion includes three or more levels.<sup>3</sup> The requestor stated that pelvic fixation is also considered in shorter level fusion procedures in clinical scenarios when there is increased risk of fusion failure, including patients with high pelvic incidence (PI), high body mass index (BMI), and conditions with sagittal plane deformity such as spondylolisthesis. The requestor stated that surgeons performing revision lumbar surgery to treat an existing pseudarthrosis (that is, nonunion or failed fusion) commonly include pelvic fixation to provide additional stability in these challenging clinical situations.

According to the requestor, although pelvic fixation strategies and implants have evolved since they were first introduced in the 1970s, including the development of sacro-alar-iliac (SAI) screws in 2007,<sup>4</sup> challenges with pelvic

fixation persist. Studies indicate a 17%–23% complication rate, including screw or rod breakages, loose screws, L5–S1 pseudoarthrosis, and high revision rates.<sup>5–6</sup> Many patients also experience sacroiliac (SI) joint pain and degeneration after multilevel fusions to the sacrum.<sup>7</sup> The SI joint often exhibits pathological increased motion in spinal deformity patients<sup>8</sup> and continues to move even after single-implant pelvic fixation<sup>9–10</sup> leading to suboptimal outcomes and loss of correction.

The requestor stated that currently, greater biomechanical loads are being placed on spinopelvic constructs and surgeons are performing an increasing number of multilevel fusions. Evolving surgical techniques and instrumentation now allow for treatment of more severe deformities, as well as the performance of surgery on patients with a higher BMI and poor bone quality. According to the requestor, the iFuse Bedrock™ Granite Implant System represents a next-generation solution that allows for both

pelvic fixation and sacroiliac joint fusion. The requestor stated this implant is the first Food and Drug Administration (FDA) cleared device designed for both purposes,<sup>11</sup> featuring a composite construction that includes a strong inner threaded screw component and a 3D-printed porous fusion sleeve to promote osseointegration. The requestor reported that there have been no reported breakages of the implant in over 8,500 cases.<sup>12</sup>

The requestor asserted the iFuse Bedrock™ Granite Implant System provides clinical advantages such as immediate and durable stability of the spinal instrumentation construct, reducing the likelihood of implant breakage due to its larger diameter and stronger construction. The requestor stated the porous fusion sleeve facilitates osseous integration, enhancing stability over time as it is designed for permanent fusion of the SI joint. Per the requestor, multiple implants can be placed on each side, either connected to a single rod or to separate rods, providing multiple points of fixation across the SI joints which increases construct stability and decreases SI joint motion. According to the requestor, the iFuse Bedrock™ Granite Implant System requires no changes to physician workflow, requires no additional surgical dissection, does not increase surgical time, or alter the length of hospital stay. The requestor stated that the iFuse Bedrock™ Granite Implant System is cleared for use with two navigation systems most frequently used in surgical facilities across the country.

The ICD–10–PCS codes that may be reported to describe the iFuse Bedrock™ Granite tulip connector device are:

<sup>11</sup> U.S. Food and Drug Administration. 510(k) Premarket Notification: iFuse Bedrock Granite™ Implant System. Published May 26, 2022. Accessed October 15, 2024. [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K220195](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K220195)

<sup>12</sup> Eastlack RK, Menger RP, Turner JD, Ashcraft KR, Carlton Recking W, Kleck CJ. Spinopelvic Fixation Using an Osseointegrative Implant: Analysis of Postmarket Surveillance to Determine the Failure Rate. *Int J Spine Surg*. 2025 Jun 12;19(3):273–278. doi: 10.14444/8720. PMID: 39890424; PMCID: PMC12268591.

Follow-Up: E-Poster #21. Spine: Affiliated Society Meeting Abstracts 10(1):p 170, September 2009.

<sup>5</sup> Eastlack RK, Soroceanu A, Mundis GM Jr, et al. Rates of Loosening, Failure, and Revision of Iliac Fixation in Adult Deformity Surgery. *Spine (Phila Pa 1976)*. 2022;47(14):986–994. doi:10.1097/BRS.0000000000004356.

<sup>6</sup> Odland K, Chanbour H, Zuckerman SL, Polly DW Jr. Spinopelvic fixation failure in the adult spinal deformity population: systematic review and meta-analysis. *Eur Spine J*. 2024 Jul;33(7):2751–2762. doi: 10.1007/s00586-024-08241-6. Epub 2024 Apr 15. Erratum in: *Eur Spine J*. 2025 Sep 18. doi: 10.1007/s00586-025-09232-x. PMID: 38619634.

<sup>7</sup> Manzetti M, Ruffilli A, Barile F, et al. Sacroiliac Joint Degeneration and Pain After Spinal Arthrodesis: A Systematic Review. *Clin Spine Surg*. 2023;36(4):169–182. doi:10.1097/BSD.0000000000001341.

<sup>8</sup> Mikula AL, Fogelson JL, Oushy S, Pinter ZW, Peters PA, Abode-Iyamah K, Sebastian AS, Freedman B, Currier BL, Polly DW, Elder BD. Change in pelvic incidence between the supine and standing positions in patients with bilateral sacroiliac joint vacuum signs. *J Neurosurg Spine*. 2021 Jan 15;34(4):617–622. doi: 10.3171/2020.8.SPINE20742. PMID: 33450735.

<sup>9</sup> Wei C, Zuckerman SL, Cerpa M, Ma H, Yang M, Yuan S, Lenke LG. Can pelvic incidence change after spinal deformity correction to the pelvis with S2-alar-iliac screws? *Eur Spine J*. 2021 Sep;30(9):2486–2494. doi: 10.1007/s00586-020-06658-3. Epub 2020 Nov 11. PMID: 33179128.

<sup>10</sup> Cunningham BW, Sponseller PD, Murgatroyd AA, Kikkawa J, Tortolani PJ. A comprehensive biomechanical analysis of sacral alar iliac fixation: an in vitro human cadaveric model. *J Neurosurg Spine*. 2019 Jan 4;30(3):367–375. doi: 10.3171/2018.8.SPINE18328. PMID: 30611149.

<sup>2</sup> Lee CS, Chung SS, Choi SW, Yu JW, Sohn MS. Critical length of fusion requiring additional fixation to prevent nonunion of the lumbosacral junction. *Spine (Phila Pa 1976)*. 2010 Mar 15;35(6):E206–11. doi: 10.1097/BRS.0b013e3181bfa518. PMID: 20195201.

<sup>3</sup> Jankowski PP, Hashmi SZ, Lord EL, Heller JE, Essig DA, Passias PG, Tahmasebpour P, Capobianco RA, Kleck CJ, Polly DW, Zuckerman SL; Spinopelvic Study Group. Trends in Lumbosacral-Pelvic Fixation Strategies. *Int J Spine Surg*. 2025 Sep 2;19(4):402–408. doi: 10.14444/8765. PMID: 40514223.

<sup>4</sup> Kebaish, Khaled M. MD (Johns Hopkins Hospital); Gunne, Albert Pull ter MD; Mohamed, Ahmed S. MD; Zimmerman, Ryan; Ko, Phebe S. BS; Skolasky, Richard L. ScD; O'Brien, Joseph R. MD, MPH; Sponseller, Paul D. MD. A New Low Profile Sacro-Pelvic Fixation Using S2 Alar Iliac (S2AI) Screws in Adult Deformity Fusion to the Sacrum: A Prospective Study with Minimum Two-Year

| ICD-10-PCS Code | Description                                                                                                                         |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------|
| XNH6058         | Insertion of internal fixation device with tulip connector into right pelvic bone. open approach, new technology group 8            |
| XNH6358         | Insertion of internal fixation device with tulip connector into right pelvic bone, percutaneous approach, new technology group 8    |
| XNH7058         | Insertion of internal fixation device with tulip connector into left pelvic bone, open approach, new technology group 8             |
| XNH7358         | Insertion of internal fixation device with tulip connector into left pelvic bone, percutaneous approach, new technology group 8     |
| XRGE058         | Fusion of right sacroiliac joint using internal fixation device with tulip connector, open approach, new technology group 8         |
| XRGE358         | Fusion of right sacroiliac joint using internal fixation device with tulip connector, percutaneous approach, new technology group 8 |
| XRGF058         | Fusion of left sacroiliac joint using internal fixation device with tulip connector, open approach, new technology group 8          |
| XRGF358         | Fusion of left sacroiliac joint using internal fixation device with tulip connector, percutaneous approach, new technology group 8  |

The previously listed procedure codes describing “Insertion” (ICD-10-PCS codes XNH6058, XNH6358, XNH7058, and XNH7358) are assigned to MS-DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and the procedure codes describing “Fusion” (ICD-10-PCS codes XRGE058, XRGE358, XRGF058, and XRGF358) are assigned to MS-DRGs 028 (Spinal Procedures with MCC), MS-DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), and MS-DRG 030 (Spinal Procedures without CC/MCC) under MDC 01 (Diseases and Disorders of the Nervous System) and MS-DRGs 402, 426, 427, 428, 447, 448, 450, 451, 456, 457, and 458 under MDC 08. We note that because the ICD-10-PCS codes describing “Insertion” of internal fixation device with tulip connector are not assigned to one of the spinal fusion MS-DRGs as a standalone procedure, another ICD-10-PCS code describing a spinal fusion procedure would need to be reported on the same claim to group

to one of the previously listed spinal fusion MS-DRGs. We refer the reader to the ICD-10 MS-DRG Definitions Manual, Version 43.1, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software> for complete documentation of the GROUPER logic for the previously listed MS-DRGs.

For this FY 2027 IPPS/LTCH PPS proposed rule, we also received a separate, but related request, from another manufacturer of devices used in the performance of a spinal fusion procedure. Specifically, we received a request to reassign cases reporting the use of the aprevo® Intervertebral Body Fusion Device (hereafter referred to as aprevo®) from MS-DRG 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical) to MS-DRG 450 (Single Level Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device) or alternatively, to reassign cases reporting the use of aprevo® from MS-DRG 402 to MS-DRG

428, and separately, to reassign cases reporting the use of aprevo® from MS-DRG 428 to the higher severity level (with MCC) MS-DRG 426. We note that we have previously discussed the reassignment of cases reporting the use of the aprevo® technology in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26726 through 26729) and final rule (88 FR 58731 through 58735, as corrected in the FY 2024 final rule correction notice at 88 FR 77211), and in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 35971 through 39585) and final rule (89 FR 69034 through 69061). We also note that the aprevo® technology was approved for new technology add-on payments for FY 2022 (86 FR 45127 through 45133), FY 2023 (87 FR 49468 through 49469) and FY 2024 (88 FR 58802). We refer the reader to those rulemaking discussions for additional detailed information regarding the aprevo® technology.

The ICD-10-PCS codes that may be reported to describe lumbar fusion procedures that use the aprevo® device are:

| ICD-10-PCS Code | Description                                                                                                                                                           |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| XRGA0R7         | Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7                        |
| XRGA3R7         | Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7                |
| XRGA4R7         | Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7     |
| XRGB0R7         | Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7                               |
| XRGB3R7         | Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7                       |
| XRGB4R7         | Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7            |
| XRGC0R7         | Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, open approach, new technology group 7                    |
| XRGC3R7         | Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7            |
| XRGC4R7         | Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7 |
| XRGD0R7         | Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7                                    |
| XRGD3R7         | Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7                            |
| XRGD4R7         | Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7                 |

We note that for the Spring 2026 ICD-10-PCS code update, the manufacturer of the aprevo® custom-made anatomically designed interbody fusion device submitted a request to revise the descriptions for the procedure codes that describe use of the aprevo® device. The manufacturer requested that the description of the previously listed codes (and nine other procedure codes that describe a cervical fusion using a custom-made anatomically designed interbody fusion device) be revised to specifically identify that the technology is designed from a virtual anatomic model. The agenda and related meeting materials for these specific topics are available on the CMS website at: <https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials>. We note that the deadline for receipt of public comments for the proposals included in the Spring 2026 procedure code update is April 17, 2026; therefore, the final code decisions on these proposals are not yet available for inclusion in Table 6B.—New Procedure Codes associated with this FY 2027 IPPS/LTCH PPS proposed rule. Under our established process, if the new and revised procedure code proposals are finalized after review and consideration of public comments following the Spring procedure code update, the codes are specifically identified with a footnote in Table 6B.—New Procedure Codes and Table 6F.—Revised Procedure Code Titles along with the MDC, MS-DRG assignment(s), and

operating room (O.R.) or non-operating room (non-O.R.) designation that is made publicly available in association with the final rule on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps>. This established process includes initially reviewing the predecessor codes' MS-DRG assignment and designation, while considering other relevant factors (for example, severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition). The public may provide feedback on these finalized assignments, which is then taken into consideration for the following fiscal year.

Each of the previously listed procedure codes is currently assigned to MDC 01 in MS-DRGs 028, 029, and 030, and to MDC 08 in MS-DRGs 402, 426, 427, 428, 447, 448, 450, 451, 456, 457, and 458.

As previously discussed, in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36552), we noted that we would continue to consider the request to modify the GROUPE logic of MS-DRGs 426, 427, and 428 (with regard to the reassignment of cases with an ICD-10-PCS code that describes fusion of a sacroiliac joint using an internal fixation device with tulip connector or insertion of an internal fixation device with tulip connector into a pelvic bone with another spinal fusion procedure code that currently map to the lower severity level MS-DRG to the highest severity

level (with MCC) MS-DRG) in connection with future rulemaking and stated that the logic for MS-DRGs 456, 457, and 458 is defined by extensive fusions. Under ICD-10-PCS, an extensive fusion procedure is defined as a spinal fusion procedure involving 8 or more thoracic vertebral joint levels. For example, ICD-10-PCS code 0RG8070 (Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, anterior approach, anterior column, open approach) describes an extensive fusion procedure. An extensive fusion procedure may also be reported with a combination of codes (cluster) that includes at least one code describing fusion at the thoracic vertebral joint levels and at least one code describing fusion at the lumbar vertebral joint levels, such as ICD-10-PCS code 0RG7070 (Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, anterior approach, anterior column, open approach) and ICD-10-PCS code 0SG1070 (Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, anterior approach, anterior column, open approach). We refer the reader to Table 6P. 3a that is publicly available in association with this FY 2027 IPPS/LTCH PPS proposed rule on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps> for the list of procedure codes we analyzed to identify an extensive fusion that is also reflected in the ICD-10 MS-DRG Definitions

Manual, Version 43.1 under MS-DRGs 456, 457, and 458.

In review of these requests, we first analyzed claims data from the September 2025 update of the FY 2025 MedPAR file for MS-DRGs 028, 029, and 030 and for cases reporting a spinal fusion procedure with a custom-made

anatomically designed interbody fusion device, cases reporting an SI joint fusion or spinal fusion procedure with insertion of an internal fixation device with tulip connector, and cases reporting an extensive fusion. We found zero cases reporting either technology across MS-DRGs 028, 029, and 030. We

found 4 cases reporting an extensive fusion in MS-DRG 028, 4 cases reporting an extensive fusion in MS-DRG 029, and zero cases reporting an extensive fusion in MS-DRG 030. Findings from our analysis are shown in the following table.

| MS-DRG | Description                 | Number of cases | Average Length of Stay | Average costs |
|--------|-----------------------------|-----------------|------------------------|---------------|
| 028    | All cases                   | 2,067           | 12.2                   | \$54,697      |
|        | Cases with extensive fusion | 4               | 16.8                   | \$122,802     |
|        | All other cases             | 2,063           | 12.2                   | \$54,565      |
| 029    | All cases                   | 3,070           | 6.1                    | \$32,288      |
|        | Cases with extensive fusion | 4               | 6.8                    | \$31,250      |
|        | All other cases             | 3,066           | 6.1                    | \$32,289      |
| 030    | All cases                   | 861             | 3.1                    | \$20,965      |

As shown in the table, for MS-DRG 028, the four cases reporting an extensive fusion had a longer average length of stay (16.8 days versus 12.2 days) and higher average costs (\$122,802 versus \$54,697) compared to the average length of stay and average costs of all the cases in MS-DRG 028. After further review of the data we considered three of the four cases to be outlier cases (that is, unusually expensive cases) because the costs for each of the three cases exceeded \$100,000 and the length of stay for each of the three cases was twice as long or longer than the average length of stay of all the cases in MS-DRG 028. For MS-DRG 029, the four cases reporting an extensive fusion had a comparable average length of stay (6.8 days versus 6.1 days) and lower average costs (\$31,250 versus \$32,288) compared to the average length of stay and average costs of all the cases in MS-DRG 029.

We note that although the logic for case assignment to MS-DRGs 028, 029, and 030 includes procedure codes that describe a spinal fusion procedure with a custom-made anatomically designed interbody fusion device and procedure codes that describe an SI joint fusion with insertion of an internal fixation device with tulip connector, as well as procedure codes that describe an extensive fusion procedure, the MS-DRG assigned is based on an MDC 01 principal diagnosis code that describes a disease or disorder of the nervous system, therefore, we would not expect to see a significant volume of cases reporting the procedure codes that describe a spinal fusion procedure with a custom-made anatomically designed interbody fusion device, an SI joint fusion with insertion of an internal fixation device with tulip connector, or

an extensive fusion procedure in the data. Additionally, we note that the indications for the aprevo® custom-made anatomically designed interbody fusion device include adults with spinal deformities and degenerative conditions and the indications for the iFuse Bedrock™ Granite Implant System include patients with sacroiliac joint dysfunction that is a direct result of SI joint disruption and degenerative sacroiliitis as well as patients with acute, non-acute, and non-traumatic fractures involving the SI joint. The diagnosis codes describing these conditions are assigned to MDC 08, therefore, it is expected that the majority of cases reporting the procedure codes that describe a spinal fusion procedure with a custom-made anatomically designed interbody fusion device, an SI joint fusion with insertion of an internal fixation device with tulip connector, or an extensive fusion procedure would group to the MDC 08 MS-DRGs instead of to MDC 01 MS-DRGs 028, 029, and 030. We refer the reader to the ICD-10 MS-DRG Definitions Manual Version 43.1 (available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>) for complete documentation of the GROUPER logic for MDC 01 and MDC 08.

We then analyzed claims data for MS-DRGs 402, 426, 427, 428, 447, 448, 450, 451, 456, 457, and 458 and for: (1) cases reporting a spinal fusion procedure with a custom-made anatomically designed interbody fusion device, (2) cases reporting an SI joint fusion or spinal fusion procedure with insertion of an internal fixation device with tulip connector, (3) cases reporting a fusion

procedure with both technologies (that is, a single case reporting a procedure code describing a spinal fusion procedure with a custom-made anatomically designed interbody fusion device and another procedure code(s) describing an SI joint fusion or a spinal fusion procedure with insertion of an internal fixation device with tulip connector, (4) cases reporting an extensive fusion without either technology (that is, aprevo® or iFuse Bedrock™ Granite Implant System), (5) cases reporting an extensive fusion with a custom-made anatomically designed interbody fusion device, (6) cases reporting an extensive fusion with an SI joint fusion or spinal fusion procedure with insertion of an internal fixation device with tulip connector, and (7) cases reporting an extensive fusion with both technologies.

We note that the logic for case assignment to MS-DRGs 402, 447, 448, 450 and 451 does not include the procedure codes or the procedure code clusters that describe an extensive fusion; therefore, no data for extensive fusion cases are reflected in the table that follows for those MS-DRGs. There were also zero cases found reporting both technologies in MS-DRG 402. In addition, because the logic for case assignment to MS-DRGs 426, 447, and 450 includes the reporting of a custom-made anatomically designed interbody fusion device to group to the respective MCC severity level MS-DRG, no data for cases reporting a custom-made anatomically designed interbody fusion device are reflected in the table that follows for MS-DRGs 427, 448, and 451. Findings from our analysis are shown in the following table.

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| MS-DRG | Description                                                                                | Number of cases | Average Length of Stay | Average costs |
|--------|--------------------------------------------------------------------------------------------|-----------------|------------------------|---------------|
| 402    | All cases                                                                                  | 15,344          | 2.9                    | \$38,483      |
|        | Cases with custom-made anatomically designed interbody fusion device                       | 85              | 3.3                    | \$59,906      |
|        | Cases with internal fixation device with tulip connector                                   | 11              | 4.2                    | \$46,207      |
|        | <b>All other cases</b>                                                                     | 15,248          | 2.9                    | \$38,358      |
| 426    | All cases                                                                                  | 3,123           | 8.9                    | \$99,235      |
|        | Cases with custom-made anatomically designed interbody fusion device                       | 142             | 5.6                    | \$103,797     |
|        | Cases with internal fixation device with tulip connector                                   | 154             | 9.3                    | \$134,327     |
|        | Cases with both technologies                                                               | 22              | 7.8                    | \$112,683     |
|        | Cases with extensive fusion without either technology                                      | 532             | 10.5                   | \$128,537     |
|        | Cases with extensive fusion with custom-made anatomically designed interbody fusion device | 65              | 9.7                    | \$118,927     |
|        | Cases with extensive fusion with internal fixation device with tulip connector             | 151             | 10.8                   | \$165,523     |
|        | Cases with extensive fusion with both technologies                                         | 13              | 7.8                    | \$179,522     |
|        | <b>All other cases</b>                                                                     | 2,044           | 8.5                    | \$82,469      |
| 427    | All cases                                                                                  | 13,359          | 4.7                    | \$68,506      |
|        | Cases with internal fixation device with tulip connector                                   | 502             | 5.7                    | \$93,993      |
|        | Cases with both technologies                                                               | 0               | 0                      | \$0           |
|        | Cases with extensive fusion without either technology                                      | 1,251           | 7.1                    | \$103,226     |
|        | Cases with extensive fusion with custom-made anatomically designed interbody fusion device | 0               | 0                      | \$0           |
|        | Cases with extensive fusion with internal fixation device with tulip connector             | 247             | 7.0                    | \$129,777     |
|        | Cases with extensive fusion with both technologies                                         | 0               | 0                      | \$0           |
|        | <b>All other cases</b>                                                                     | 11,359          | 4.4                    | \$62,224      |
| 428    | All cases                                                                                  | 7,847           | 3.0                    | \$56,192      |
|        | Cases with custom-made anatomically designed interbody fusion device                       | 51              | 3.2                    | \$75,595      |
|        | Cases with internal fixation device with tulip connector                                   | 134             | 3.5                    | \$71,458      |
|        | Cases with both technologies                                                               | 0               | 0                      | \$0           |
|        | Cases with extensive fusion without either technology                                      | 138             | 4.8                    | \$81,054      |
|        | Cases with extensive fusion with custom-made anatomically designed interbody fusion device | 2               | 10.5                   | \$119,007     |
|        | Cases with extensive fusion with internal fixation device with tulip connector             | 22              | 5.5                    | \$83,447      |
|        | Cases with extensive fusion with both technologies                                         | 2               | 8.0                    | \$149,474     |
|        | <b>All other cases</b>                                                                     | 7,498           | 2.9                    | \$55,208      |
| 447    | All cases                                                                                  | 2,428           | 10.2                   | \$62,858      |
|        | Cases with custom-made anatomically designed interbody fusion device                       | 19              | 3.8                    | \$74,184      |
|        | Cases with internal fixation device with tulip connector                                   | 47              | 10.4                   | \$78,810      |
|        | Cases with both technologies                                                               | 0               | 0                      | \$0           |
|        | <b>All other cases</b>                                                                     | 2,362           | 10.3                   | \$62,450      |
| 448    | All cases                                                                                  | 13,835          | 4.1                    | \$40,716      |
|        | Cases with internal fixation device with tulip connector                                   | 258             | 4.8                    | \$62,513      |

|     |                                                                                            |        |      |           |
|-----|--------------------------------------------------------------------------------------------|--------|------|-----------|
|     | Cases with both technologies                                                               | 0      | 0    | \$0       |
|     | <b>All other cases</b>                                                                     | 13,577 | 4.1  | \$40,301  |
| 450 | All cases                                                                                  | 1,141  | 7.9  | \$48,325  |
|     | Cases with custom-made anatomically designed interbody fusion device                       | 37     | 2.5  | \$55,985  |
|     | Cases with internal fixation device with tulip connector                                   | 3      | 5.7  | \$21,440  |
|     | Cases with both technologies                                                               | 0      | 0    | \$0       |
|     | <b>All other cases</b>                                                                     | 1,101  | 8.1  | \$48,141  |
|     |                                                                                            |        |      |           |
| 451 | All cases                                                                                  | 12,475 | 3.0  | \$30,366  |
|     | Cases with internal fixation device with tulip connector                                   | 56     | 2.1  | \$27,438  |
|     | Cases with both technologies                                                               | 0      | 0    | \$0       |
|     | <b>All other cases</b>                                                                     | 12,419 | 3.1  | \$30,379  |
| 456 | All cases                                                                                  | 1,571  | 12.2 | \$79,972  |
|     | Cases with custom-made anatomically designed interbody fusion device                       | 1      | 15.0 | \$66,999  |
|     | Cases with internal fixation device with tulip connector                                   | 26     | 14.5 | \$106,983 |
|     | Cases with both technologies                                                               | 0      | 0    | \$0       |
|     | Cases with extensive fusion without either technology                                      | 584    | 11.8 | \$92,132  |
|     | Cases with extensive fusion with custom-made anatomically designed interbody fusion device | 0      | 0    | \$0       |
|     | Cases with extensive fusion with internal fixation device with tulip connector             | 60     | 12.7 | \$136,660 |
|     | Cases with extensive fusion with both technologies                                         | 0      | 0    | \$0       |
|     | <b>All other cases</b>                                                                     | 900    | 12.3 | \$67,537  |
| 457 | All cases                                                                                  | 3,706  | 6.0  | \$56,069  |
|     | Cases with custom-made anatomically designed interbody fusion device                       | 5      | 3.4  | \$67,984  |
|     | Cases with internal fixation device with tulip connector                                   | 39     | 5.5  | \$57,500  |
|     | Cases with both technologies                                                               | 0      | 0    | \$0       |
|     | Cases with extensive fusion without either technology                                      | 1,354  | 6.3  | \$66,745  |
|     | Cases with extensive fusion with custom-made anatomically designed interbody fusion device | 0      | 0    | \$0       |
|     | Cases with extensive fusion with internal fixation device with tulip connector             | 121    | 6.6  | \$91,823  |
|     | Cases with extensive fusion with both technologies                                         | 0      | 0    | \$0       |
|     | <b>All other cases</b>                                                                     | 2,187  | 5.7  | \$47,428  |
| 458 | All cases                                                                                  | 1,265  | 2.7  | \$40,771  |
|     | Cases with custom-made anatomically designed interbody fusion device                       | 7      | 2.9  | \$64,086  |
|     | Cases with internal fixation device with tulip connector                                   | 8      | 3.1  | \$60,041  |
|     | Cases with both technologies                                                               | 0      | 0    | \$0       |
|     | Cases with extensive fusion without either technology                                      | 143    | 4.3  | \$57,964  |
|     | Cases with extensive fusion with custom-made anatomically designed interbody fusion device | 0      | 0    | \$0       |
|     | Cases with extensive fusion with internal fixation device with tulip connector             | 10     | 4.2  | \$62,304  |
|     | Cases with extensive fusion with both technologies                                         | 0      | 0    | \$0       |
|     | <b>All other cases</b>                                                                     | 1,097  | 2.5  | \$38,044  |

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The findings show that the cases reporting a spinal fusion procedure with the custom-made anatomically designed interbody fusion device, cases reporting an SI joint fusion or spinal fusion

procedure with an internal fixation device with tulip connector, and cases reporting both technologies generally had higher average costs with variation in the average length of stay in comparison to the average costs and

average length of stay of all the cases in their respective MS-DRG. The findings also show that cases reporting an extensive spinal fusion procedure with or without either of the technologies had average costs that are higher in

comparison to the average costs of all the cases in their respective MS-DRG and generally had a comparable or longer average length of stay in comparison to the average length of stay of all the cases in their respective MS-DRG.

With regard to the request to reassign cases reporting a spinal fusion procedure with the custom-made anatomically designed interbody fusion device from MS-DRG 402 to MS-DRG 450 and the alternative request to reassign cases reporting a spinal fusion procedure with the custom-made anatomically designed interbody fusion device from MS-DRG 402 to MS-DRG 428, we note that MS-DRG 402 is a base MS-DRG and therefore is not subdivided into severity level subgroups. Additionally, the logic for MS-DRG 402 is defined by single level combined anterior and posterior spinal fusion procedures (except cervical) and the logic for MS-DRG 428 is defined by multiple level combined anterior and posterior spinal fusion procedures. Therefore, the reassignment of cases reporting the use of a custom-made anatomically designed interbody fusion device from MS-DRG 402 to MS-DRG 428 would not be feasible and would not be consistent with the logic of these recently formed MS-DRGs which is intended to differentiate a single level combined anterior and posterior fusion from a multiple level combined anterior and posterior spinal fusion. As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69058 through 69059), in response to public comments, we previously reviewed a request to reassign cases from the then proposed MS-DRG 402 to the then proposed MS-DRG 428 (both subsequently finalized) from this same manufacturer.

Although the findings from our analysis show that the average costs of the cases reporting the use of a custom-made anatomically designed interbody fusion device in MS-DRG 402 are higher compared to all the cases in MS-DRG 402 (\$59,906 versus \$38,483) with a longer average length of stay (3.3 days versus 2.9 days), and are more similar to the average costs of all the cases in MS-DRG 450 which are \$48,325 with an average length of stay of 7.9 days, we disagree with the requested reassignment of cases reporting a spinal fusion procedure with the custom-made anatomically designed interbody fusion device from MS-DRG 402 to MS-DRG 450 because MS-DRG 450 is subdivided into two severity level subgroups and defined by single level spinal fusions (except cervical), meaning either the anterior column of the spine or the posterior column of the spine is fused

in a single operative episode. As previously discussed, the logic for case assignment to MS-DRG 402 reflects single level combined anterior and posterior spinal fusion procedures, meaning both the anterior column of the spine and the posterior column of the spine are fused in a single operative episode. MS-DRG 402 is also not subdivided into severity levels. As such, the logic for case assignment to MS-DRGs 402 and 450 reflects two different types of spinal fusions that are clinically distinct procedures with different resources.

As shown in our review of the requested reassignment of cases reporting the use of a custom-made anatomically designed interbody fusion device from MS-DRG 428 to MS-DRG 426, the average costs of the 51 cases in MS-DRG 428 are higher compared to all the cases in MS-DRG 428 (\$75,595 versus \$56,192) with a comparable average length of stay (3.2 days versus 3.0 days), and the average costs of all the cases in MS-DRG 426 are \$99,235 with an average length of stay of 8.9 days. However, we also note that there are 142 cases reporting the use of a custom-made anatomically designed interbody fusion device in MS-DRG 426 with average costs of \$103,797 and an average length of stay of 5.6 days. Because the logic for MS-DRG 426 includes cases that are reassigned from MS-DRG 427 reporting the use of a custom-made anatomically designed interbody fusion device with a CC, we expanded our analysis to identify how many of the 142 cases would otherwise have grouped to MS-DRG 427 in the absence of the current logic. Of the 142 cases reporting the use of a custom-made anatomically designed interbody fusion device in MS-DRG 426, we found 22 cases were reported with an MCC secondary diagnosis with average costs of \$143,062 and an average length of stay of 8.8 days and 120 cases were reported with a CC secondary diagnosis with average costs of \$96,598 and an average length of stay of 5.1 days. We note that, as reflected in the previously displayed table, the average costs of all the cases in MS-DRG 427 is \$68,506.

As shown in our review of MS-DRG 426, the 154 cases reporting a fusion procedure with an internal fixation device with tulip connector had average costs of \$134,327 with an average length of stay of 9.3 days in comparison to the average costs of all the cases in MS-DRG 426 of \$99,235 with an average length of stay of 8.9 days. We also recognized a similar pattern in MS-DRGs 427, 428, 447, 448, 456, 457, and 458 where the average costs for cases reporting a fusion procedure with an

internal fixation device with tulip connector had higher average costs and a longer or comparable average length of stay compared to the average costs and average length of stay of all the cases in their respective MS-DRG.

Relatedly, our findings for cases reporting an extensive fusion without either technology and our findings for cases reporting an extensive fusion with either or both technologies for MS-DRGs 426, 427, and 428 and MS-DRGs 456, 457, and 458 demonstrate higher average costs in comparison to the average costs of all the cases in their respective MS-DRG, including at the MCC level. Specifically, our data analysis shows that cases reporting an extensive fusion without either technology currently grouping to MS-DRGs 426, 427, and 428 have higher average costs (\$128,537, \$103,226, and \$81,054, respectively) compared to the average costs of all the cases in their respective MS-DRG (\$99,235, \$68,506, and \$56,192, respectively). Similarly, cases reporting an extensive fusion without either technology currently grouping to MS-DRGs 456, 457, and 458 have higher average costs (\$92,132, \$66,745, and \$57,964, respectively) compared to the average costs of all the cases in their respective MS-DRG (\$79,972, \$56,069, and \$40,771, respectively). Our data analysis also shows that cases reporting an extensive fusion with either or both technologies currently grouping to MS-DRGs 426, 427, and 428 have higher average costs compared to the average costs of all the cases in their respective MS-DRG. Overall, the 229 cases ( $65 + 151 + 13 = 229$ ) in MS-DRG 426 reporting an extensive fusion with either or both technologies have average costs of \$153,092 and an average length of stay of 10.3 days compared to the average cost and average length of stay of all the cases in MS-DRG 426 (\$99,235 and 8.9 days, respectively). The 247 cases in MS-DRG 427 reporting an extensive fusion with either or both technologies have costs of \$129,777 and a length of stay of 7.0 days compared to the average cost and average length of stay of all the cases in MS-DRG 427 (\$68,506 and 4.7 days, respectively). The 26 cases ( $2 + 22 + 2 = 26$ ) in MS-DRG 428 reporting an extensive fusion with either or both technologies have average costs of \$91,261 and an average length of stay of 6.1 days compared to the average cost and average length of stay of all the cases in MS-DRG 428 (\$56,192 and 3.0 days, respectively). Additionally, cases reporting an extensive fusion with either or both technologies currently grouping to MS-DRGs 456, 457, and 458



have higher costs and a longer length of stay compared to the average costs and average length of stay of all the cases in their respective MS-DRG. The 60 cases in MS-DRG 456 reporting an extensive fusion with either or both technologies have a cost of \$136,660 and a length of stay of 12.7 days, the 121 cases in MS-DRG 457 reporting an extensive fusion with either or both technologies have a cost of \$91,823 and a length of stay of 6.6 days, and the 10 cases in MS-DRG 458 reporting an extensive fusion with either or both technologies have a cost of \$62,304 and a length of stay of 4.2 days.

Based on our review and analysis, we disagree with the requested reassignment of cases from the lower severity level to the higher severity level MS-DRG for cases reporting use of the aprevo® custom-made anatomically designed interbody fusion device, as well as for cases reporting use of the iFuse Bedrock™ Granite Implant System. We believe that each

technology is indicated for use in complex spinal fusion procedures and requires increased resource utilization. If we were to reassign cases from the lower severity level to the higher severity level, that would not account for the cases at the MCC level that are unable to be reassigned. Specifically, the cases reporting use of the aprevo® custom-made anatomically designed interbody fusion device and cases reporting use of the iFuse Bedrock™ Granite Implant System at the MCC level would continue to have higher average costs and a longer average length of stay compared to all the other cases at the MCC level.

We also believe that extensive spinal fusion procedures, with or without the use of either or both technologies, also demonstrate increased resource utilization because extensive spinal fusion procedures address various spinal deformities across multiple spinal vertebral joint levels.

As such, to address the differences in resource utilization and additional treatment options for the patients whose spinal condition requires an extensive fusion procedure or a complex spinal fusion procedure that uses either the aprevo® custom-made anatomically designed interbody fusion device or the iFuse Bedrock™ Granite Implant System, we are proposing a new base MS-DRG.

Consistent with our established process as discussed in section II.C.1.b. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, once the decision has been made to propose to make further modifications to the MS-DRGs, such as creating a new base MS-DRG, all five criteria to create subgroups must be met for the base MS-DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS-DRG. We note that, as shown in the table that follows, a three-way split of this proposed new base MS-DRG was met.

| Proposed New MS-DRGs | Number of Cases | Average Length of Stay | Average Costs |
|----------------------|-----------------|------------------------|---------------|
| With MCC             | 1,613           | 11.1                   | \$117,743     |
| With CC              | 3,997           | 6.4                    | \$87,683      |
| Without CC/MCC       | 692             | 3.8                    | \$65,891      |

For the proposed new MS-DRGs for cases reporting an extensive fusion or a complex spinal fusion procedure with either the aprevo® custom-made anatomically designed interbody fusion device or the iFuse Bedrock™ Granite Implant System, there is at least (1) 500 cases in the MCC group, 500 cases in the with CC group, and 500 cases in the without CC/MCC group; (2) 5 percent of the cases in the MCC group, 5 percent of the cases in the CC group, and 5 percent of the cases in the without CC/MCC group; (3) a 20 percent difference in average costs between the MCC group, the CC group, and the without CC/MCC group; (4) a \$2,000 difference in average costs between the MCC group, the CC group, and the without CC/MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS-DRG in capturing differences in expected cost between the proposed MS-DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

Therefore, for FY 2027, we are proposing to create new MS-DRGs 523, 524, and 525 (Extensive or Complex Spinal Fusion Procedures Except Cervical with MCC, with CC, and without CC/MCC, respectively).

Specifically, we are proposing to reassign cases reporting an extensive spinal fusion procedure from MS-DRGs 426, 427, 428, 456, 457 and 458 and to reassign cases reporting a spinal fusion procedure with use of the aprevo® custom-made anatomically designed interbody fusion device or the iFuse Bedrock™ Granite Implant System from MS-DRGs 402, 426, 427, 428, 447, 448, 450, 451, 456, 457 and 458 to proposed new MS-DRGs 523, 524, and 525. We are also proposing to revise the titles for MS-DRGs 426, 447, and 450 to remove the reference to “Custom-made Anatomically Designed Interbody Fusion Device” and to revise the titles for MS-DRGs 456, 457, and 458 to remove the reference to “Extensive Fusions”. We note that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule.

#### b. Hip or Knee Procedures With Periprosthetic Joint Infection

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18049 through 18052) and final rule (90 FR 36606 through 36610), we discussed a request we received to reassign cases reporting a hip or knee procedure with a principal diagnosis of periprosthetic joint

infection (PJI) from the lower severity level “without CC/MCC” MS-DRG to the higher severity level “with CC” MS-DRG when there is no major complication or comorbidity (MCC) or complication or comorbidity (CC) reported for the following MS-DRGs; MS-DRGs 463, 464, and 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC, with CC, and without CC/MCC, respectively), MS-DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively), MS-DRGs 474, 475, and 476 (Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC, with CC, and without CC/MCC, respectively), MS-DRGs 480, 481, and 482 (Hip and Femur Procedures Except Major Joint with MCC, with CC, and without CC/MCC, respectively) and MS-DRG 485, 486, and 487 (Knee Procedures with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively). We stated that, based on our review and analysis of the data, we disagreed with the request to reassign PJI cases from the lower severity “without CC/MCC” level MS-DRG to the higher severity “with CC” level MS-DRG suggested by the requestor as the

average costs of the PJI cases in the “without CC/MCC” level were not comparable and did not align with the average costs of all the cases at the “with CC” level. We stated we believed that MS-DRGs 466, 467, and 468 appeared to group appropriately in their respective MS-DRG assignments and noted that the logic for case assignment to MS-DRGs 485, 486, and 487 includes a principal diagnosis of infection and the difference in average costs for the cases reporting a PJI with a hip or knee procedure compared to the average costs of all the cases in their respective MS-DRG was minimal. We stated we believed the data support proposing a new base MS-DRG for the cases reporting a PJI with a hip or knee procedure in MS-DRGs 463, 464, 465, 474, 475, 476, 480, 481, and 482 to better reflect the complexity of services, resource utilization, and severity of illness of these patients. We applied the criteria to create subgroups in a base MS-DRG as discussed in section II.C.1.b. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18014 through 18015) and final rule (90 FR 36553 through 36554) and noted that the criteria for a two-way split was met. Therefore, for FY 2026 we proposed to create new MS-DRGs 403 and 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC and without MCC, respectively).

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36608 through 36610), several commenters expressed support for the proposal to create proposed new MS-DRGs 403 and 404, however, a commenter stated they encountered inconsistencies when grouping cases using the Version 43 test GROUPPER that was made publicly available in association with the FY 2026 IPPS/LTCH PPS proposed rule on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>. The commenter also stated they found an overlap of approximately 52 procedure codes among the list of procedure codes analyzed by CMS made publicly available in Table 6P.6a in connection with the proposed rule analysis and also listed in the logic for MS-DRGs 466, 467, and 468 included in the Draft Version 43 ICD-10 MS-DRG Definitions Manual. The commenter stated it was unable to reconcile some of the shifts in case volume from the MS-DRGs that were analyzed and those that shifted into the proposed new MS-DRGs because it was not clear if the cases

shifted because of the procedure code overlap or because of programming within the Version 43 test GROUPPER.

We acknowledged the commenter's findings and noted that under the GROUPPER software program, some collections of ICD-10-PCS procedure codes have a different set of attributes, independent of those of the codes that make them up (that is, their “components”). We stated that these collections of ICD-10-PCS procedure codes are called clusters and that a routine program in the GROUPPER, upstream of the MS-DRG assignment logic, searches the claim for clusters. We noted that when a cluster is found, it is added to the list of procedures found on the claim. We stated that clusters may be “restricted” by Major Diagnostic Category (MDC) and a restricted cluster inhibits the use of its procedure code component attributes for the MDC's MS-DRG assignment logic. We provided the example that procedure code cluster 0SPC0JZ (Removal of synthetic substitute from right knee joint, open approach) and 0SRT0JZ (Replacement of right knee joint, femoral surface with synthetic substitute, open approach) may be recognized on a claim if both codes appear (in any order) and the reporting of these codes creates a new procedure code cluster “@0045”. We stated that the cluster @0045 has a different set of attributes than either code 0SPC0JZ or 0SRT0JZ by itself and is further “restricted” for MDC 08. We noted that when the GROUPPER logic determines that the MDC is 08, it ignores the attributes of procedure codes 0SPC0JZ and 0SRT0JZ individually, only using those of @0045. We indicated in that example how the logic results in assignment of the claim to MS-DRGs 466, 467, and 468 rather than MS-DRGs 463, 464, and 465. We stated that if the principal diagnosis reported is not assigned under MDC 08, the cluster would not restrict the interpretation of the component codes and their individual attributes could be relevant as well as those of @0045.

As also discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36610), following publication of the FY 2026 IPPS/LTCH PPS proposed rule, we identified that the intended grouping of cases to the proposed new MS-DRGs 403 and 404 was impacted because of these cluster restrictions under MDC 08; therefore, we removed the restrictions and performed additional analysis. As a result of removing the restrictions, and due to the existing overlapping procedure code logic among a subset of the MDC 08 MS-DRGs, our analysis showed that further redistribution of the cases under MDC 08 occurred,

impacting the remaining number of cases in MS-DRGs 466, 467, and 468 and MS-DRGs 485, 486, and 487, such that, those MS-DRGs no longer satisfied the criteria for a 3-way split. We noted that under our established process for applying the criteria to create subgroups within a base MS-DRG, existing MS-DRGs 466, 467, and 468 would be deleted and a new base MS-DRG for Revision of Hip or Knee Replacement would be established. Additionally, we noted that under this established process, existing MS-DRGs 485, 486, and 487 would be deleted and new MS-DRGs (2-way split) for Knee Procedures with Principal Diagnosis of Infection with and without MCC, respectively, would be established. Because these findings associated with removal of the MDC 08 restrictions on the procedure code clusters for existing MS-DRGs 466, 467, and 468 and MS-DRGs 485, 486, and 487 were not identified until after publication of the proposed rule, in addition to having an updated test Gropper that reflected these potential changes, we did not finalize the creation of proposed new MS-DRGs 403 and 404 for FY 2026. We stated that we may further consider these potential MS-DRG changes for future rulemaking. We refer the reader to the FY 2026 IPPS/LTCH PPS proposed and final rulemaking discussions for additional detailed information.

As also discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18012 through 18013) and final rule (90 FR 36550 through 36552), we received a request to modify the GROUPPER logic of MS-DRGs 463, 464, and 465; MS-DRGs 466, 467, and 468; and MS-DRGs 492, 493, and 494 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with ICD-10-PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) that currently map to the lower severity level MS-DRG to the highest severity level (with MCC) MS-DRG. We noted that the procedure to insert a bone void filler is designated as a non-operating room (Non-O.R.) procedure and stated our belief that the key factor that would contribute to resource utilization in these cases is the fact that the patients have an infection(s) which require additional resources. We further noted that, as discussed in section II.C.5.a. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18049 through 18052), we received an MS-DRG request related to cases reporting a hip or knee procedure with

a diagnosis of PJI in MS-DRGs 463, 464, and 465 (the same set of MS-DRGs that were submitted to analyze ICD-10-PCS code XW0V0P7). We stated that in our review of the claims data to address that specific request we noted that a subset of the cases also reported procedure code XW0V0P7 and for these reasons and those previously described, we believed additional time was needed to review and evaluate potential extensive modifications to the structure of these MS-DRGs.

As we discuss further in this section, based on our analysis of the September 2025 update of the FY 2025 MedPAR file for this FY 2027 IPPS/LTCH PPS proposed rule, we continue to believe it is appropriate to propose new MS-DRGs 403 and 404 to better differentiate and reflect the complexity of services, resource utilization, and severity of illness for patients diagnosed with a PJI. For purposes of our analysis for this FY 2027 IPPS/LTCH PPS proposed rule, in connection with the FY 2026 IPPS/LTCH PPS final rule discussion related to the findings about the restriction logic and overlap of procedure codes, for proposed new MS-DRGs 403 and 404 for FY 2027, we removed the restriction logic under MDC 08 for the procedure code clusters within MS-DRGs 466, 467, and 468, and within MS-DRGs 485, 486, and 487. These changes are reflected in the test version of the ICD-10 MS-DRG Grouper Software, Version 44, and the draft version of the ICD-10 MS-DRG Definitions Manual, Version 44, available in association with this FY 2027 IPPS/LTCH PPS proposed rule (available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>) so that the public can better analyze and understand the impact of the proposals as summarized in the discussion that follows.

Additionally, for this FY 2027 IPPS/LTCH PPS proposed rule, in connection with the FY 2026 IPPS/LTCH PPS final rule discussion related to the request for reassignment of cases with ICD-10-PCS code XW0V0P7 that currently map to the lower severity level MS-DRG to the highest severity level (with MCC) MS-DRG, the requestor submitted a revised request. Specifically, in addition to the previously listed MS-DRGs identified for CMS' consideration for FY 2026, the requestor added MDC 08 MS-DRGs 474, 475, and 476 and MS-DRGs 480, 481, and 482, that are also the subject of the request to reassign cases reporting a hip or knee procedure with a principal diagnosis of PJI from the lower severity

level "without CC/MCC" MS-DRG to the higher severity level "with CC" MS-DRG, and further added MDC 08 MS-DRGs 477, 478, and 479 (Biopsies of Musculoskeletal System and Connective Tissue with MCC, with CC, and without CC/MCC, respectively). We also note that separately, this same requestor submitted a request for the reassignment of cases reporting ICD-10-PCS code XW0V0P7 that currently map to the lower severity level MS-DRG to the highest severity level (with MCC) MS-DRG within MDC 10 for MS-DRGs 616, 617, and 618 (Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC, with CC, without CC/MCC, respectively) and MS-DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, without CC/MCC, respectively) that is discussed separately in section II.C.5 of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule.

Effective October 1, 2021, ICD-10-PCS code XW0V0P7 was created in association with a new technology add-on payment application for CERAMENT® G, a combination device-drug product intended to treat bone infections (for example, osteomyelitis). It is an implantable bone void filler that consists of hydroxyapatite and calcium sulfate, as well as gentamicin sulfate, which is an antibacterial agent. We refer the reader to the September 8, 2020 ICD-10 Coordination and Maintenance Committee meeting materials available on the CMS website at: <https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials> for information regarding the procedure code request, including a transcript of the discussion and the related meeting materials. We also note that CERAMENT® G was approved for a new technology add-on payment beginning October 1, 2022 for the indication of infection which expired on September 30, 2025. For FY 2026, CERAMENT® G was approved for a new technology add-on payment for the indication of an open fracture. We refer the reader to section II.E.4. of the preamble of the FY 2026 IPPS/LTCH PPS proposed and final rules for additional discussion regarding CERAMENT® G in association with the new technology add-on payment indication.

For the Spring 2026 ICD-10-PCS code update, the manufacturer of CERAMENT® G submitted a request for a new code to describe another antibiotic-eluting bone void filler product, CERAMENT® V, in association with a new technology add-on payment application for FY 2027. We refer the

reader to section II.E.6. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule for additional discussion regarding CERAMENT® V in association with the new technology add-on payment policy. The manufacturer also requested a revision to the existing code, ICD-10-PCS code XW0V0P7, that is reported to identify the administration of CERAMENT® G. CERAMENT® V is an injectable synthetic bone void filler that consists of hydroxyapatite, calcium sulfate, and the antibiotic vancomycin hydrochloride. The manufacturer requested that the description of existing ICD-10-PCS code XW0V0P7 be revised to specifically identify gentamicin and that a new code be created to specifically identify vancomycin in association with the new technology add-on payment application. The agenda and related materials for these specific topics are available on the CMS website at: <https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials>. We note that the deadline for receipt of public comments for the proposals included in the Spring 2026 procedure code update is April 17, 2026; therefore, the final code decisions on these proposals are not yet available for inclusion in Table 6B.—New Procedure Codes associated with this FY 2027 IPPS/LTCH PPS proposed rule. Under our established process, if the new and revised procedure code proposals are finalized after review and consideration of public comments following the Spring update, the codes are specifically identified with a footnote in Table 6B.—New Procedure Codes and Table 6F.—Revised Procedure Code Titles along with the MDC, MS-DRG assignment(s), and operating room (O.R.) or non-operating room (non-O.R.) designation that is made publicly available in association with the final rule on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps>. This established process includes initially reviewing the predecessor codes MS-DRG assignment and designation, while considering other relevant factors (for example, severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition). The public may provide feedback on these finalized assignments, which is then taken into consideration for the following fiscal year.

Accordingly, to continue our analysis of cases reporting a hip or knee procedure with a principal diagnosis of

PJI as discussed in the FY 2026 IPPS/LTCH PPS final rule with removal of the restriction logic and to address the request to modify the GROUPER logic by reassigning cases with ICD-10-PCS code XW0V0P7 that currently map to the lower severity level MS-DRG to the highest severity level (with MCC) MS-DRG, we reviewed claims data from the September 2025 update of the FY 2025 MedPAR file for MS-DRGs 463, 464, 465, 466, 467, 468, 474, 475, 476, 477, 478, 479, 480, 481, 482, 485, 486, 487, 492, 493, and 494 and for: 1) cases reporting a principal diagnosis of PJI with a hip or knee procedure based on

the proposed logic as reflected in Table 6P.3b, 2) cases reporting the insertion of antibiotic-eluting bone void filler (code XW0V0P7) without a principal diagnosis of PJI among all the cases in the respective MS-DRG (that is, not limited to the proposed logic reflected in Table 6P.3b), and 3) cases reporting both a principal diagnosis of PJI with a hip or knee procedure and ICD-10-PCS code XW0V0P7 based on the proposed logic as reflected in Table 6P.3b. We refer the reader to Table 6P. 3b that is publicly available in association with this FY 2027 IPPS/LTCH PPS proposed rule on the CMS website at: [https://](https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps)

[www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps](https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps) for the list of diagnosis codes we analyzed to identify a PJI, for the procedure code we analyzed to identify the insertion of antibiotic-eluting bone void filler, and for the list of procedure codes we analyzed from the previously listed MS-DRGs (excluding MS-DRGs 477, 478, and 479 that were not the subject of the request) to identify a hip or knee procedure. Findings from our analysis with removal of the restriction logic are shown in the following table.

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| MS-DRG | Description                                                                       | Number of cases | Average Length of Stay | Average costs |
|--------|-----------------------------------------------------------------------------------|-----------------|------------------------|---------------|
| 463    | All cases                                                                         | 9,360           | 11.0                   | \$44,308      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure                  | 3,262           | 11.0                   | \$44,259      |
|        | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 37              | 11.6                   | \$58,390      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 37              | 12.8                   | \$66,398      |
|        | <b>All other cases</b>                                                            | 6,024           | 11.1                   | \$44,112      |
| 464    | All cases                                                                         | 25,312          | 4.8                    | \$29,451      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure                  | 7,107           | 6.0                    | \$30,776      |
|        | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 62              | 7.9                    | \$42,191      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 55              | 7.7                    | \$53,840      |
|        | <b>All other cases</b>                                                            | 18,088          | 4.3                    | \$28,813      |
| 465    | All cases                                                                         | 15,298          | 1.9                    | \$23,216      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure                  | 1,539           | 3.7                    | \$26,422      |
|        | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 13              | 3.4                    | \$37,878      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 6               | 4.7                    | \$37,250      |
|        | <b>All other cases</b>                                                            | 13,740          | 1.7                    | \$22,837      |
| 466    | All cases                                                                         | 233             | 7.8                    | \$45,156      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure                  | 0               | 0.0                    | \$0           |
|        | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 1               | 7.0                    | \$65,185      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 0               | 0.0                    | \$0           |
|        | <b>All other cases</b>                                                            | 232             | 7.8                    | \$45,070      |
| 467    | All cases                                                                         | 1,191           | 3.9                    | \$34,165      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure                  | 0               | 0.0                    | \$0           |
|        | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 6               | 3.7                    | \$56,375      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 0               | 0.0                    | \$0           |
|        | <b>All other cases</b>                                                            | 1,185           | 3.9                    | \$34,053      |
| 468    | All cases                                                                         | 703             | 2.0                    | \$30,588      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure                  | 0               | 0.0                    | \$0           |
|        | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 0               | 0.0                    | \$0           |
|        | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 0               | 0.0                    | \$0           |
|        | <b>All other cases</b>                                                            | 703             | 2.0                    | \$30,588      |
| 474    | All cases                                                                         | 2,333           | 12.2                   | \$36,126      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure                  | 95              | 13.8                   | \$37,558      |
|        | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 15              | 11.6                   | \$44,350      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 3               | 18.0                   | \$55,079      |
|        | <b>All other cases</b>                                                            | 2,220           | 12.1                   | \$35,984      |
| 475    | All cases                                                                         | 2,751           | 7.5                    | \$20,485      |
|        | Cases with principal diagnosis of PJI with hip or knee procedure                  | 207             | 7.9                    | \$27,205      |

|     |                                                                                   |        |      |          |
|-----|-----------------------------------------------------------------------------------|--------|------|----------|
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 17     | 9.6  | \$38,015 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 2      | 8.5  | \$31,397 |
|     | <b>All other cases</b>                                                            | 2,525  | 7.5  | \$19,807 |
| 476 | All cases                                                                         | 329    | 3.3  | \$10,428 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure                  | 21     | 3.8  | \$14,176 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 0      | 0.0  | \$0      |
|     | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 0      | 0.0  | \$0      |
|     | <b>All other cases</b>                                                            | 308    | 3.3  | \$10,172 |
|     |                                                                                   |        |      |          |
| 477 | All cases                                                                         | 3,142  | 10.2 | \$31,429 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 9      | 11.4 | \$35,531 |
|     | <b>All other cases</b>                                                            | 3,133  | 10.2 | \$31,417 |
| 478 | All cases                                                                         | 5,332  | 6.5  | \$22,446 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 41     | 6.6  | \$28,786 |
|     | <b>All other cases</b>                                                            | 5,291  | 6.5  | \$22,397 |
| 479 | All cases                                                                         | 887    | 4.1  | \$17,157 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 7      | 2.9  | \$11,760 |
|     | <b>All other cases</b>                                                            | 880    | 4.1  | \$17,200 |
| 480 | All cases                                                                         | 25,136 | 7.1  | \$26,366 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure                  | 115    | 10.6 | \$34,940 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 14     | 7.4  | \$46,859 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 0      | 0.0  | \$0      |
|     | <b>All other cases</b>                                                            | 25,007 | 7.1  | \$26,341 |
| 481 | All cases                                                                         | 61,471 | 4.8  | \$19,579 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure                  | 181    | 7.1  | \$23,982 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 12     | 5.3  | \$36,464 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 0      | 0.0  | \$0      |
|     | <b>All other cases</b>                                                            | 61,278 | 4.8  | \$19,563 |
| 482 | All cases                                                                         | 13,347 | 3.4  | \$15,230 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure                  | 29     | 4.4  | \$17,640 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 3      | 3.7  | \$27,391 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 0      | 0.0  | \$0      |
|     | <b>All other cases</b>                                                            | 13,315 | 3.4  | \$15,222 |
| 485 | All cases                                                                         | 646    | 10.0 | \$29,585 |
|     | Cases with principal diagnosis of PJI with knee procedure                         | 218    | 9.8  | \$32,871 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 0      | 0.0  | \$0      |
|     | Cases with principal diagnosis of PJI with knee procedure and code XW0V0P7        | 2      | 16.0 | \$84,670 |
|     | <b>All other cases</b>                                                            | 426    | 10.1 | \$27,645 |
| 486 | All cases                                                                         | 1,332  | 6.4  | \$18,960 |
|     | Cases with principal diagnosis of PJI with knee procedure                         | 394    | 6.4  | \$23,058 |

|     |                                                                                   |        |      |          |
|-----|-----------------------------------------------------------------------------------|--------|------|----------|
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 2      | 7.6  | \$20,822 |
|     | Cases with principal diagnosis of PJI with knee procedure and code XW0V0P7        | 2      | 8.0  | \$38,624 |
|     | <b>All other cases</b>                                                            | 934    | 6.4  | \$17,185 |
| 487 | All cases                                                                         | 312    | 4.5  | \$13,801 |
|     | Cases with principal diagnosis of PJI with knee procedure                         | 62     | 4.0  | \$20,903 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 0      | 0.0  | \$0      |
|     | Cases with principal diagnosis of PJI with knee procedure and code XW0V0P7        | 0      | 0.0  | \$0      |
|     | <b>All other cases</b>                                                            | 250    | 4.6  | \$12,040 |
| 492 | All cases                                                                         | 5,806  | 8.1  | \$32,889 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure                  | 17     | 13.2 | \$58,792 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 26     | 9.5  | \$46,746 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 0      | 0.0  | \$0      |
|     | <b>All other cases</b>                                                            | 5,763  | 8.1  | \$32,750 |
| 493 | All cases                                                                         | 17,072 | 5.1  | \$23,555 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure                  | 43     | 6.2  | \$29,352 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 58     | 5.7  | \$34,714 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 0      | 0.0  | \$0      |
|     | <b>All other cases</b>                                                            | 16,971 | 5.1  | \$23,502 |
| 494 | All cases                                                                         | 7,229  | 3.3  | \$18,846 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure                  | 5      | 2.6  | \$15,251 |
|     | Cases with code XW0V0P7 without a principal diagnosis of PJI                      | 12     | 2.5  | \$20,387 |
|     | Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7 | 0      | 0.0  | \$0      |
|     | <b>All other cases</b>                                                            | 7,212  | 3.3  | \$18,846 |

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The findings show that with removal of the restriction logic from MS-DRGs 466, 467, and 468 there are zero cases reporting a principal diagnosis of PJI with a hip or knee procedure in MS-DRGs 466, 467, and 468. With removal of the restriction logic, the cases that previously grouped to MS-DRGs 466, 467, and 468 are redistributed to MS-DRGs 463, 464, and 465 based on the proposed Version 44 GROUPER logic and the surgical hierarchy. Under the current ICD-10 MS-DRGs Version 43.1, procedure code 0SP90JZ (Removal of synthetic substitute from right hip joint, open approach) is listed in the logic for case assignment to MS-DRGs 463, 464, and 465 and is also listed as part of a code cluster with procedure code 0SR9019 (Replacement of right hip joint with metal synthetic substitute, cemented, open approach) in the logic for case assignment to MS-DRGs 466, 467, and 468. With removal of the cluster restriction logic in MS-DRGs 466, 467, and 468, cases reporting

procedure code 0SP90JZ with a principal diagnosis assigned to MDC 08 will group to MS-DRGs 463, 464, and 465 under the proposed ICD-10 MS-DRGs, Version 44. The findings also show that with removal of the restriction logic from MS-DRGs 485, 486, and 487 further redistribution of the cases occurs. Specifically, cases that previously grouped to MS-DRGs 485, 486, and 487 now group or “shift” to other MS-DRGs. As a result, the remaining number of cases in MS-DRGs 466, 467, and 468 and MS-DRGs 485, 486, and 487 is reduced and those MS-DRGs no longer satisfy the criteria for a 3-way split under application of our established criteria for subgroups consistent with the discussion in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36610).

The findings show that for the cases reporting a principal diagnosis of PJI with a hip or knee procedure in MS-DRGs 463, 464, 465, 474, 475, 476, 480, 481, 482, 485, 486, 487, 492, and 493, the average length of stay is generally

comparable or longer compared to the average length of stay of all the cases in their respective MS-DRG. Findings from our analysis also show that the average costs of the cases reporting a principal diagnosis of PJI with a hip or knee procedure in MS-DRGs 464, 465, 474, 475, 476, 480, 481, 482, 485, 486, 487, 492, and 493 are higher compared to the average costs of all the cases in their respective MS-DRG. We note that the average length of stay and the average costs of the 5 cases reporting a PJI with a hip or knee procedure in MS-DRG 494 are shorter than (2.6 days versus 3.3 days) the average length of stay and lower than (\$15,251 versus \$18,846) the average costs of all the cases in MS-DRG 494. We also note that the average costs of the 3,262 cases reporting a principal diagnosis of PJI with a hip or knee procedure in MS-DRG 463 are approximately \$49 less than the average costs of all the cases in MS-DRG 463 (\$44,259 versus \$44,308). For the cases reporting procedure code XW0V0P7 without a principal diagnosis of PJI in

MS-DRGs 463, 464, 465, 466, 467, 474, 475, 477, 478, 480, 481, 482, 486, 492, and 493, we found that the average length of stay is generally comparable or longer compared to the average length of stay of all the cases in their respective MS-DRG. We note that there were zero cases found reporting procedure code XW0V0P7 without a principal diagnosis of PJI in MS-DRGs 468 and 476. Findings from our analysis also show that the average costs of the cases reporting procedure code XW0V0P7 without a principal diagnosis of PJI in MS-DRGs 463, 464, 465, 466, 467, 474, 475, 477, 478, 480, 481, 482, 486, 492, 493, and 494 are higher compared to the average costs of all the cases in their respective MS-DRG. We also note that the 7 cases in MS-DRG 479 have a shorter average length of stay (2.9 days versus 4.1 days) and lower average costs (\$11,760 versus \$17,157) compared to the average length of stay and average costs of all the cases in MS-DRG 479. As shown in the table, the cases reporting procedure code XW0V0P7 without a principal diagnosis of PJI in the lower severity level MS-DRGs (that is, MS-DRGs 464, 465, 475, 478, 481, 482, 493, and 494) have average costs that overall, are more aligned with the average costs of all the cases at the respective higher severity level (with MCC) MS-DRG (that is MS-DRGs 463, 474, 477, 480, and 492). For example, the 62 cases in MS-DRG 464 and the 13 cases in MS-DRG 465 reporting procedure code XW0V0P7 without a principal diagnosis of PJI have average costs of \$42,191 and \$37,878 respectively, compared to the average costs of \$44,308 for all the cases in MS-DRG 463.

Lastly, for the cases reporting both a principal diagnosis of PJI with a hip or knee procedure and ICD-10-PCS code XW0V0P7 in MS-DRGs 463, 464, 465, 474, 475, 485, and 486, we found that the average length of stay is longer and the average costs are comparable or

higher compared to the average length of stay and average costs of the cases reporting a principal diagnosis of PJI with a hip or knee procedure without ICD-10-PCS code XW0V0P7, as well as compared to all the cases in their respective MS-DRG.

Based on our review and analysis of the data, we believe the data support proposing a new base MS-DRG for the cases reporting a PJI with a hip or knee procedure to better differentiate and reflect the complexity of services, resource utilization, and severity of illness of these patients. In connection with our review and analysis of the data, we note that under the current ICD-10 MS-DRGs Version 43.1, diagnosis codes T84.53XA (Infection and inflammatory reaction due to internal right knee prosthesis, initial encounter) and T84.54XA (Infection and inflammatory reaction due to internal left knee prosthesis, initial encounter) are listed in the logic for case assignment to MS-DRGs 485, 486, and 487, and are also listed in Table 6P.3b in association with this FY 2027 IPPS/LTCH PPS proposed rule as they describe a PJI of the knee and were included in our analysis previously discussed. Therefore, we believe it is appropriate to propose to remove these codes from the logic for case assignment to MS-DRGs 485, 486, and 487 in association with the removal of the restriction logic so that cases reporting a PJI with a knee procedure from those MS-DRGs appropriately group to the proposed new base MS-DRG.

We also note that, as previously described, procedure code XW0V0P7 is currently designated as a non-O.R. procedure. Because our analysis of the data supports the reassignment of cases reporting procedure code XW0V0P7 without a principal diagnosis of PJI from the lower severity level (without CC/MCC or with CC) to the higher (with MCC) severity level, we are proposing to redesignate procedure code XW0V0P7

from a non-O.R. procedure to a non-O.R. procedure affecting the MS-DRG assignment at the higher with MCC severity level for MS-DRGs 463, 474, 477, 480, and 492. We further note that because the data show that the cases reporting both a principal diagnosis of PJI with a hip or knee procedure and ICD-10-PCS code XW0V0P7 in MS-DRGs 463, 464, 465, 474, 475, 485, and 486 have a longer average length of stay and higher average costs compared to the average length of stay and average costs of the cases reporting a principal diagnosis of PJI with a hip or knee procedure alone (without ICD-10-PCS code XW0V0P7), with the proposed redesignation of code XW0V0P7 from non-O.R. to non-O.R. affecting the MS-DRG, these cases reporting ICD-10-PCS code XW0V0P7 would also be reassigned at the highest severity level in connection with a new base MS-DRG proposal and consistent with the proposal for assignment to MS-DRGs 463, 474, 477, 480, and 492 previously discussed. As such, the data support proposing a new base MS-DRG for cases reporting a principal diagnosis of PJI with a hip or knee procedure with or without procedure code XW0V0P7.

Consistent with our established process as discussed in section II.C.1.b. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, once the decision has been made to propose to make further modifications to the MS-DRGs, such as creating a new base MS-DRG, all five criteria to create subgroups must be met for the base MS-DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS-DRG. We note that, as shown in the table that follows, a three-way split of this proposed new base MS-DRG failed to meet the criterion that there is at least a 20% difference in average costs in the without CC/MCC group. The following table illustrates our findings.

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| <b>Proposed New MS-DRGs</b> | <b>Number of Cases</b> | <b>Average Length of Stay</b> | <b>Average Costs</b> |
|-----------------------------|------------------------|-------------------------------|----------------------|
| <b>With MCC</b>             | 3,653                  | 11.1                          | \$44,365             |
| <b>With CC</b>              | 7,655                  | 6.1                           | \$30,755             |
| <b>Without CC/MCC</b>       | 1,626                  | 3.7                           | \$26,142             |

As discussed in section II.C.1.b. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the

“with MCC and without MCC” subgroups and found that all five criteria were met. The following table illustrates our findings and reflects a simulation of the proposed new MS-DRG 403 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic

Joint Infection with MCC or Insertion of Antibiotic-eluting Bone Void Filler) and MS-DRG 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC).



| Proposed New MS-DRGs | Number of Cases | Average Length of Stay | Average Costs |
|----------------------|-----------------|------------------------|---------------|
| With MCC             | 3,653           | 11.1                   | \$44,365      |
| Without MCC          | 9,281           | 5.7                    | \$29,947      |

For the proposed new MS-DRGs to identify cases reporting a PJI with a hip or knee procedure with or without procedure code XW0V0P7, there is at least (1) 500 cases in the MCC group and 500 cases in the without MCC group; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC group; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a \$2,000 difference in average costs between the MCC group and the without

MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS-DRG in capturing differences in expected cost between the proposed MS-DRG severity level splits by at least 3-percent and thus improve the overall accuracy of the IPPS payment system.

As also previously discussed, in connection with the proposed removal of the restriction logic and findings from our analysis, existing MS-DRGs 466, 467, and 468 and MS-DRGs 485, 486,

and 487 would no longer meet the criteria for a 3-way split under our established process for applying the criteria to create subgroups within a base MS-DRG. We note that, as shown in the table that follows, a three-way split for MS-DRGs 466, 467, and 468 failed to meet the criterion that there be at least 500 cases in the MCC group and that there is at least a 20% difference in average cost between the CC and NonCC group. The following table illustrates our findings.

| MS-DRGs              | Number of Cases | Average Length of Stay | Average Costs |
|----------------------|-----------------|------------------------|---------------|
| 466 - With MCC       | 232             | 7.8                    | \$45,070      |
| 467 - With CC        | 1,185           | 3.9                    | \$34,053      |
| 468 - Without CC/MCC | 703             | 2.0                    | \$30,588      |

As discussed in section II.C.1.b. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for

a two-way split. We therefore applied the criteria for a two-way split for the “with MCC and without MCC” subgroups and found that a two-way split for these MS-DRGs failed to meet

the criterion that there be at least 500 cases in the MCC group. The following table illustrates our findings.

| MS-DRGs               | Number of Cases | Average Length of Stay | Average Costs |
|-----------------------|-----------------|------------------------|---------------|
| 466 - With MCC        | 232             | 7.8                    | \$45,070      |
| 467/468 - Without MCC | 1,888           | 3.2                    | \$32,763      |

We then applied the criteria for a two-way split for the “with CC/MCC” and “without CC/MCC” subgroups. As

shown in the table that follows, a two-way split of this base MS-DRG failed to meet the criterion that there be at least

a 20% difference in average cost between the with CC/MCC and the without CC/MCC group.

| MS-DRGs               | Number of Cases | Average Length of Stay | Average Costs |
|-----------------------|-----------------|------------------------|---------------|
| 466/467 - With CC/MCC | 1,417           | 4.5                    | \$35,857      |
| 468 - Without CC/MCC  | 703             | 2.0                    | \$30,588      |

We are therefore proposing to delete MS-DRGs 466, 467, and 468 and proposing to create new base MS-DRG 449 (Revision of Hip or Knee Replacement). We also note that following our analysis previously described that reflects removal of the restriction logic for MS-DRGs 466, 467, and 468, we identified 20 procedure codes that are listed individually in the logic for case assignment to MS-DRGs 466, 467, and 468 that are also listed separately in the logic with another procedure code as a code cluster. For

example, procedure code 0SPE0JZ (Removal of synthetic substitute from left hip joint, acetabular surface, open approach) is listed individually and is also listed separately with procedure code 0SRB019 (Replacement of left hip joint with metal synthetic substitute, cemented, open approach) as a code cluster. We refer the reader to the ICD-10 MS-DRG Definitions Manual Version 43.1, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/>

*ms-drg-classifications-and-software* for complete documentation of the Grouper logic for MS-DRGs 466, 467, and 468. To appropriately reflect the logic list for proposed new base MS-DRG 449 under the proposed ICD-10 MS-DRGs, Version 44, and to ensure cases group appropriately in connection with the proposed changes to the ICD-10 MS-DRGs for FY 2027, we are proposing to remove the following 20 procedure codes from the logic list as individually listed codes.

| ICD-10-PCS Code | Description                                                                                                |
|-----------------|------------------------------------------------------------------------------------------------------------|
| 0SPA0JZ         | Removal of synthetic substitute from right hip joint, acetabular surface, open approach                    |
| 0SPA4JZ         | Removal of synthetic substitute from right hip joint, acetabular surface, percutaneous endoscopic approach |
| 0SPC0JC         | Removal of synthetic substitute from right knee joint, patellar surface, open approach                     |
| 0SPC4JC         | Removal of synthetic substitute from right knee joint, patellar surface, percutaneous endoscopic approach  |
| 0SPD0JC         | Removal of synthetic substitute from left knee joint, patellar surface, open approach                      |
| 0SPD4JC         | Removal of synthetic substitute from left knee joint, patellar surface, percutaneous endoscopic approach   |
| 0SPE0JZ         | Removal of synthetic substitute from left hip joint, acetabular surface, open approach                     |
| 0SPE4JZ         | Removal of synthetic substitute from left hip joint, acetabular surface, percutaneous endoscopic approach  |
| 0SPR0JZ         | Removal of synthetic substitute from right hip joint, femoral surface, open approach                       |
| 0SPR4JZ         | Removal of synthetic substitute from right hip joint, femoral surface, percutaneous endoscopic approach    |
| 0SPS0JZ         | Removal of synthetic substitute from left hip joint, femoral surface, open approach                        |
| 0SPS4JZ         | Removal of synthetic substitute from left hip joint, femoral surface, percutaneous endoscopic approach     |
| 0SPT0JZ         | Removal of synthetic substitute from right knee joint, femoral surface, open approach                      |
| 0SPT4JZ         | Removal of synthetic substitute from right knee joint, femoral surface, percutaneous endoscopic approach   |
| 0SPU0JZ         | Removal of synthetic substitute from left knee joint, femoral surface, open approach                       |
| 0SPU4JZ         | Removal of synthetic substitute from left knee joint, femoral surface, percutaneous endoscopic approach    |
| 0SPV0JZ         | Removal of synthetic substitute from right knee joint, tibial surface, open approach                       |
| 0SPV4JZ         | Removal of synthetic substitute from right knee joint, tibial surface, percutaneous endoscopic approach    |
| 0SPW0JZ         | Removal of synthetic substitute from left knee joint, tibial surface, open approach                        |
| 0SPW4JZ         | Removal of synthetic substitute from left knee joint, tibial surface, percutaneous endoscopic approach     |

The following table illustrates our simulation of proposed new MS-DRG 449.

| Proposed New MS-DRG | Number of Cases | Average Length of Stay | Average Costs |
|---------------------|-----------------|------------------------|---------------|
| MS-DRG 449          | 983             | 4.8                    | \$30,657      |

We then applied the criteria to MS-DRGs 485, 486, and 487 in connection with the proposed removal of the

restriction logic. We note that, as shown in the table that follows, a three-way split for MS-DRGs 485, 486, and 487

failed to meet the criterion that there be at least 500 cases in the MCC group. The following table illustrates our findings.

| MS-DRGs              | Number of Cases | Average Length of Stay | Average Costs |
|----------------------|-----------------|------------------------|---------------|
| 485 - With MCC       | 426             | 10.1                   | \$27,645      |
| 486 - With CC        | 934             | 6.4                    | \$17,185      |
| 487 - Without CC/MCC | 250             | 4.6                    | \$12,040      |

As discussed in section II.C.1.b. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for

a two-way split. We therefore applied the criteria for a two-way split for the “with MCC and without MCC” groups. We note that, as shown in the table that follows, a two-way split for these MS-

DRGs failed to meet the criterion that there be at least 500 cases in the MCC group. The following table illustrates our findings.

| MS-DRGs               | Number of Cases | Average Length of Stay | Average Costs |
|-----------------------|-----------------|------------------------|---------------|
| 485 - With MCC        | 426             | 10.1                   | \$27,645      |
| 486/487 - Without MCC | 1,184           | 6.0                    | \$16,099      |

We are therefore proposing to delete MS-DRGs 485, 486, and 487 and proposing to create new base MS-DRG

400 (Knee Procedures with Principal Diagnosis of Infection). The following

table illustrates our simulation of the proposal.

| Proposed New MS-DRGs | Number of Cases | Average Length of Stay | Average Costs |
|----------------------|-----------------|------------------------|---------------|
| MS-DRG 400           | 1,555           | 6.9                    | \$18,142      |

In summary, for FY 2027, we are proposing to (1) remove the restriction logic for MS-DRGs 466, 467, and 468 and MS-DRGs 485, 486, and 487, (2) remove ICD-10-CM diagnosis codes T84.53XA and T84.54XA from the logic for case assignment to MS-DRGs 485, 486, and 487, (3) delete MS-DRGs 466, 467, and 468 and MS-DRGs 485, 486, and 487, (4) create new base MS-DRG 449 and new base MS-DRG 400 with the logic lists as reflected in Tables 6P.3c and 6P.3d, respectively, that is available in association with this FY

2027 IPPS/LTCH PPS proposed rule, (5) redesignate procedure code XW0V0P7 from non-O.R. to non-O.R. affecting specified MS-DRGs as discussed in this section of this FY 2027 IPPS/LTCH PPS proposed rule, (6) create new MS-DRG 403 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC or Insertion of Antibiotic-eluting Bone Void Filler) to reflect cases reporting a hip or knee procedure with a principal diagnosis of PJI and the reassignment of cases reporting ICD-10-PCS code XW0V0P7

from the lower severity level to the higher (with MCC) severity level and create new MS-DRG 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC) with the logic lists as reflected in Table 6P.3b, and (7) reassign cases reporting ICD-10-PCS code XW0V0P7 from the lower severity level (without CC/MCC or with CC) to the higher (with MCC) severity level and revise the titles to the following MS-DRGs to reflect the proposed reassignment.

| Current Description                                                                                                  | Proposed Description                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MS-DRG 463 Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC | MS-DRG 463 Wound Debridement or Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler |
| MS-DRG 474 Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC                            | MS-DRG 474 Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler                           |
| MS-DRG 477 Biopsies of Musculoskeletal System and Connective Tissue with MCC                                         | MS-DRG 477 Biopsies of Musculoskeletal System and Connective Tissue with MCC or Insertion of Antibiotic-eluting Bone Void Filler                                        |
| MS-DRG 480 Hip and Femur Procedures Except Major Joint with MCC                                                      | MS-DRG 480 Hip and Femur Procedures Except Major Joint with MCC or Insertion of Antibiotic-eluting Bone Void Filler                                                     |
| MS-DRG 492 Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC                                | MS-DRG 492 Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC or Insertion of Antibiotic-eluting Bone Void Filler                               |

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We note that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule.

We also note that the titles for MS-DRGs 463, 464, and 465 reflect “Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC, with CC, and without CC/MCC”, respectively. We believe the term “and” in these MS-DRG titles may be misleading as it implies that both a wound debridement and skin graft need to be reported to satisfy the logic for case assignment to these MS-DRGs. However, the logic for case assignment to MS-DRGs 463, 464, and 465 is satisfied when either a procedure code

describing a wound debridement or a procedure code describing a skin graft (except hand) from the logic list is reported. Therefore, we are proposing to revise the term “and” to “or” for the titles for MS-DRGs 463, 464, and 465. These proposed title changes are reflected in the test version of the ICD-10 MS-DRG GROUPER Software, Version 44, and the draft version of the ICD-10 MS-DRG Definitions Manual, Version 44, available in association with this FY 2027 IPPS/LTCH PPS proposed rule (available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drug-classifications-and-software>).

5. MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): CERAMENT® G Antibiotic-Eluting Bone Void Filler

As discussed in the preamble of section II.C.4. of this FY 2027 IPPS/LTCH PPS proposed rule, we received a request to reassign cases reporting ICD-10-PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) from the lower severity level MS-DRG to the highest severity level (with MCC) MS-DRG within MDC 10 for MS-DRGs 616, 617, and 618 (Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC, with CC, without CC/MCC, respectively) and MS-DRGs 628, 629, and 630 (Other Endocrine,

Nutritional and Metabolic O.R. Procedures with MCC, with CC, without CC/MCC, respectively).

As also discussed in the preamble of section II.C.4 of this FY 2027 IPPS/LTCH PPS proposed rule, ICD-10-PCS code XW0V0P7 was created effective October 1, 2021, in association with a new technology add-on payment application for CERAMENT® G, a combination device-drug product intended to treat bone infections (for example, osteomyelitis). It is an implantable bone void filler that consists of hydroxyapatite and calcium sulfate, as well as gentamicin sulfate, which is an antibacterial agent. We refer the reader to the September 8, 2020 ICD-10 Coordination and Maintenance Committee meeting materials available on the CMS website at: <https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials> for information regarding the procedure code request, including a transcript of the discussion and the related meeting materials. We also note that CERAMENT® G was approved for a new technology add-on payment beginning October 1, 2022 for the indication of infection which expired on September 30, 2025. For FY 2026, CERAMENT® G was approved for a new technology add-on payment for the indication of an open fracture. We refer the reader to section II.E.4. of the preamble of the FY 2026 IPPS/LTCH PPS proposed and final rules for additional discussion regarding CERAMENT® G in association with the new technology add-on payment indication.

In the preamble of section II.C.4 of this FY 2027 IPPS/LTCH PPS proposed rule we also noted that for the Spring 2026 ICD-10-PCS code update, the manufacturer of CERAMENT® G submitted a request for a new code to describe another antibiotic-eluting bone void filler product, CERAMENT® V, in association with a new technology add-on payment application for FY 2027. We refer the reader to section II.E.6. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule for additional discussion regarding CERAMENT® V in association with the new technology add-on payment policy. The manufacturer also requested a revision to the existing code, ICD-10-PCS code XW0V0P7, that is reported to identify the administration of CERAMENT® G. CERAMENT® V is an injectable synthetic bone void filler that consists of hydroxyapatite, calcium sulfate, and the antibiotic vancomycin

hydrochloride. The manufacturer requested that the description of existing ICD-10-PCS code XW0V0P7 be revised to specifically identify gentamicin and that a new code be created to specifically identify vancomycin in association with the new technology add-on payment application. The agenda and related meeting materials for these specific topics are available on the CMS website at: <https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials>. We note that the deadline for receipt of public comments for the proposals included in the Spring 2026 procedure code update is April 17, 2026; therefore, the final code decisions on these proposals are not yet available for inclusion in Table 6B.—New Procedure Codes associated with this FY 2027 IPPS/LTCH PPS proposed rule. Under our established process, if the new and revised procedure code proposals are finalized after review and consideration of public comments following the Spring update, the codes are specifically identified with a footnote in Table 6B.—New Procedure Codes and Table 6F.—Revised Procedure Code Titles along with the MDC, MS-DRG assignment(s), and operating room (O.R.) or non-operating room (non-O.R.) designation that is made publicly available in association with the final rule on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps>. This established process includes initially reviewing the predecessor codes MS-DRG assignment and designation, while considering other relevant factors (for example, severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition). The public may provide feedback on these finalized assignments, which is then taken into consideration for the following fiscal year.

The requestor (the manufacturer) stated that the occurrence and economic burden of osteomyelitis is significant and diabetes has been driving the increase in osteomyelitis incidence over time, with the incidence of diabetes-related osteomyelitis rising from 2.3 to 10.5 cases per 100,000 person-years from the 1970s to the 1990s as reported by the Mayo Clinic. The requestor reported that the incidence of foot osteomyelitis among patients with diabetes mellitus is estimated to be approximately 0.3% per year, with a lifetime risk of 4%, and 68% of patients

with diabetes-related foot osteomyelitis needing an amputation. Studies indicate many individuals are readmitted to the hospital within 1 year of the amputation due to complications of the affected limb.

In addition to diabetic foot ulcers, the requestor stated that the incidence of fracture-associated osteomyelitis varies from 1.8% to 27% depending on the bone involved and the grade/type of fracture. According to the requestor, clinical trials demonstrate that the overall incidence of osteomyelitis may continue to rise due to multiple factors including improved diagnosis, increasing patient risk factors such as diabetes, and increased needs for arthroplasties. Per the requestor, re-hospitalization and treatment for osteomyelitis has significant costs to both the individual and healthcare systems, impacting quality of life and the ability to work.

The requestor stated that the antimicrobial properties of CERAMENT® G combat antimicrobial resistance, thereby effectively reducing the recurrence of infection. The requestor also stated that these antimicrobial properties have been shown to achieve good infection prevention with a shortened course of systemic antibiotics that does not extend beyond seven days.

The requestor performed its own analysis using Medicare claims data across a subset of MS-DRGs for cases reporting the use of CERAMENT® G with ICD-10-PCS code XW0V0P7 and acknowledged that the volume of cases is small, however, it also stated that its findings reflected that claims reporting the use of CERAMENT® G have higher resource utilization compared to claims that did not report the use of CERAMENT® G. Of the MS-DRGs analyzed, the requestor stated the cases reporting ICD-10-PCS code XW0V0P7 in the lower severity level MS-DRG had standardized costs that were more aligned with the costs of the higher severity level MS-DRG sequenced above it. The requestor stated its belief that the data demonstrate cases reporting ICD-10-PCS code XW0V0P7 should be reassigned to the higher MCC level MS-DRG within the MS-DRG groupings requested.

We reviewed claims data from the September 2025 update of the FY 2025 MedPAR file for MS-DRGs 616, 617, 618, 628, 629, and 630 and for cases reporting ICD-10-PCS code XW0V0P7. Findings from our analysis are shown in the following table.

| MS-DRG | Description             | Number of cases | Average Length of Stay | Average costs |
|--------|-------------------------|-----------------|------------------------|---------------|
| 616    | All cases               | 3,568           | 10.9                   | \$30,212      |
|        | Cases with code XW0V0P7 | 33              | 12.8                   | \$47,082      |
|        | <b>All other cases</b>  | 3,535           | 10.9                   | \$30,055      |
| 617    | All cases               | 9,868           | 6.5                    | \$16,621      |
|        | Cases with code XW0V0P7 | 68              | 9.9                    | \$28,916      |
|        | <b>All other cases</b>  | 9,800           | 6.5                    | \$16,536      |
| 618    | All cases               | 42              | 3.9                    | \$11,028      |
|        | Cases with code XW0V0P7 | 0               | 0                      | \$0           |
|        | <b>All other cases</b>  | 42              | 3.9                    | \$11,028      |
| 628    | All cases               | 2,904           | 10.6                   | \$32,481      |
|        | Cases with code XW0V0P7 | 29              | 14.3                   | \$43,839      |
|        | <b>All other cases</b>  | 2,875           | 10.6                   | \$32,366      |
| 629    | All cases               | 3,435           | 6.9                    | \$19,605      |
|        | Cases with code XW0V0P7 | 73              | 7.6                    | \$28,764      |
|        | <b>All other cases</b>  | 3,362           | 6.9                    | \$19,406      |
| 630    | All cases               | 122             | 2.6                    | \$12,383      |
|        | Cases with code XW0V0P7 | 0               | 0                      | \$0           |
|        | <b>All other cases</b>  | 122             | 2.6                    | \$12,383      |

The findings show that the cases reporting ICD-10-PCS code XW0V0P7 in MS-DRGs 616, 617, 628, and 629 have a longer average length of stay and higher average costs compared to all the cases in their respective MS-DRGs. We note there were zero cases reporting ICD-10-PCS code XW0V0P7 in MS-DRGs 618 and 630.

Based on our review and analysis of the data, we agree with the requestor that the average costs of the cases reporting ICD-10-PCS code XW0V0P7 at the lower severity level are more aligned with the average costs of the cases at the higher MCC severity level. To better reflect the resource utilization and severity of illness of patients with diabetic osteomyelitis, we are proposing to reassign cases reporting ICD-10-PCS code XW0V0P7 from the lower severity (without CC/MCC and with CC) MS-DRGs to the higher severity (MCC) level MS-DRG.

As previously discussed, there were no cases found in our analysis reporting ICD-10-PCS code XW0V0P7 in MS-DRGs 618 and 630 at the “without CC/MCC” level, however, if any cases reporting ICD-10-PCS code XW0V0P7 potentially grouped to MS-DRGs 618 or 630 in the future, we would anticipate those cases also demonstrating higher average costs compared to all the cases in their respective MS-DRG.

Therefore, for FY 2027, we are proposing to reassign cases reporting procedure code XW0V0P7 from the lower severity level MS-DRGs 617 and 618 to the higher severity (MCC) level MS-DRG 616 and from the lower severity level MS-DRGs 629 and 630 to the higher severity (MCC) level MS-DRG 628. We are also proposing to revise the title of MS-DRG 616 from “Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC” to “Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler” and to revise the title of MS-DRG 628 from “Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC” to “Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC or Insertion of Antibiotic-eluting Bone Void Filler” to reflect the reassignment of cases reporting procedure code XW0V0P7.

6. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)

a. Prostatectomy

Consistent with our annual review of the MS-DRGs, we identified that the current GROUPER logic for MDC 11 MS-DRGs 665, 666, and 667 (Prostatectomy with MCC, with CC, and

without CC/MCC, respectively) contains a logic list referred to as “OPERATING ROOM PROCEDURES” that includes 14 ICD-10-PCS procedure codes describing the destruction, excision, and resection of the prostate and also includes eight ICD-10-PCS procedure code combinations or procedure code “clusters” that, when reported together, satisfy the logic for assignment to MS-DRGs 665, 666, and 667. The code combinations are represented by two ICD-10-PCS procedure codes and include one ICD-10-PCS code for the resection of the prostate with one ICD-10-PCS code for the resection of bilateral seminal vesicles.

We refer the reader to the ICD-10 MS-DRG Definitions Manual Version 43.1, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>, for complete documentation of the GROUPER logic for MDC 11 MS-DRGs 665, 666, and 667.

The eight ICD-10-PCS procedure code combinations currently assigned to MDC 11 MS-DRGs 665, 666, and 667 that identify the resection of the prostate with the resection of bilateral seminal vesicles are shown in the following table:

| ICD-10-PCS Code     | Description                                                               |
|---------------------|---------------------------------------------------------------------------|
| 0VT00ZZ and 0VT30ZZ | Resection of prostate, open approach                                      |
|                     | Resection of bilateral seminal vesicles, open approach                    |
| 0VT00ZZ and 0VT34ZZ | Resection of prostate, open approach                                      |
|                     | Resection of bilateral seminal vesicles, percutaneous endoscopic approach |
| 0VT04ZZ and 0VT30ZZ | Resection of prostate, percutaneous endoscopic approach                   |
|                     | Resection of bilateral seminal vesicles, open approach                    |
| 0VT04ZZ and 0VT34ZZ | Resection of prostate, percutaneous endoscopic approach                   |
|                     | Resection of bilateral seminal vesicles, percutaneous endoscopic approach |
| 0VT07ZZ and 0VT30ZZ | Resection of prostate, via natural or artificial opening                  |
|                     | Resection of bilateral seminal vesicles, open approach                    |
| 0VT07ZZ and 0VT34ZZ | Resection of prostate, via natural or artificial opening                  |
|                     | Resection of bilateral seminal vesicles, percutaneous endoscopic approach |
| 0VT08ZZ and 0VT30ZZ | Resection of prostate, via natural or artificial opening endoscopic       |
|                     | Resection of bilateral seminal vesicles, open approach                    |
| 0VT08ZZ and 0VT34ZZ | Resection of prostate, via natural or artificial opening endoscopic       |
|                     | Resection of bilateral seminal vesicles, percutaneous endoscopic approach |

As we examined the GROUPER logic that would determine the assignment of a case to MDC 11 MS-DRGs 665, 666, and 667, we noted that ICD-10-PCS codes 0VT00ZZ, 0VT04ZZ, 0VT07ZZ and 0VT08ZZ that describe the resection of the prostate, differing only in approach, are assigned to MS-DRGs 665, 666, and 667 as standalone procedures, as well as being included in the eight procedure code combinations listed previously in these same MS-DRGs. We note that the GROUPER software program will recognize codes 0VT00ZZ, 0VT04ZZ, 0VT07ZZ and 0VT08ZZ and assign MS-DRGs 665, 666, and 667 even when a procedure code describing the resection of the bilateral seminal vesicles is not also reported, when the other parameters of the GROUPER logic are met. As procedure codes 0VT00ZZ, 0VT04ZZ, 0VT07ZZ and 0VT08ZZ are assigned to MS-DRGs 665, 666, and 667 as standalone procedures, specific assignment of these procedure codes in procedure code combinations in MS-DRGs 665, 666, and 667 is not required.

Therefore, for FY 2027, we are proposing to remove the eight ICD-10-PCS procedure code combinations listed previously from the GROUPER logic of MDC 11 MS-DRGs 665, 666, and 667 (Prostatectomy with MCC, with CC, and without CC/MCC, respectively).

#### b. Islet Cell Transplantation

As discussed in section II.C.11.b.1 of this FY 2027 IPPS/LTCH PPS proposed

rule, we received a request to change the designation of ICD-10-PCS code XW033DA (Introduction of donislelelujn allogeneic pancreatic islet cellular suspension into peripheral vein, percutaneous approach, new technology group 10) from a non-O.R. procedure to an O.R. procedure. In the ICD-10 MS-DRGs Definitions Manual Version 43.1, procedure code XW033DA is currently designated as a non-O.R. procedure affecting assignment to MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively).

In our review of the GROUPER logic of MS-DRGs 673, 674, and 675, we noted that the logic for case assignment to MS-DRGs 673, 674, and 675 as displayed in the ICD-10 MS-DRG Version 43.1 Definitions Manual (which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>) is comprised of seven logic lists. The first logic list is entitled “Operating Room Procedures” and is defined by a list of 1,754 ICD-10-PCS procedure codes describing surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in MDC 11. The second and third logic lists are entitled “or Principal Diagnosis” and are defined by the 25 ICD-10-CM diagnosis codes. The fourth logic list is entitled “with Secondary Diagnosis” and is defined by

ICD-10-CM diagnosis codes N18.5 (Chronic kidney disease, stage 5) and N18.6 (End stage renal disease). The fifth logic list is entitled “and Non-Operating Room Procedures” and is defined by a list of 30 ICD-10-PCS procedure codes describing the insertion of totally implantable vascular access devices (TIVADs) and tunneled vascular access devices. The second, third, and fourth logic lists are the components of the special logic in MS-DRGs 673, 674, and 675 for certain MDC 11 diagnoses reported with procedure codes for the insertion of tunneled or totally implantable vascular access devices.

The sixth logic list entitled “or Principal Diagnosis” is defined by ICD-10-CM diagnosis codes E10.21 (Type 1 diabetes mellitus with diabetic nephropathy), E10.22 (Type 1 diabetes mellitus with diabetic chronic kidney disease) and E10.29 (Type 1 diabetes mellitus with other diabetic kidney complication) and the seventh logic list entitled “and Non-Operating Room Procedures” is defined by the 11 ICD-10-PCS procedure codes describing the introduction of pancreatic islet cells listed in the following table. These 11 procedure codes are all designated as non-O.R. procedures affecting assignment to MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively).

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| ICD-10-PCS Code | Description                                                                                                                                          |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3E030U0         | Introduction of autologous pancreatic islet cells into peripheral vein, open approach                                                                |
| 3E030U1         | Introduction of nonautologous pancreatic islet cells into peripheral vein, open approach                                                             |
| 3E033U0         | Introduction of autologous pancreatic islet cells into peripheral vein, percutaneous approach                                                        |
| 3E033U1         | Introduction of nonautologous pancreatic islet cells into peripheral vein, percutaneous approach                                                     |
| 3E0J3U0         | Introduction of autologous pancreatic islet cells into biliary and pancreatic tract, percutaneous approach                                           |
| 3E0J3U1         | Introduction of nonautologous pancreatic islet cells into biliary and pancreatic tract, percutaneous approach                                        |
| 3E0J7U0         | Introduction of autologous pancreatic islet cells into biliary and pancreatic tract, via natural or artificial opening                               |
| 3E0J7U1         | Introduction of nonautologous pancreatic islet cells into biliary and pancreatic tract, via natural or artificial opening                            |
| 3E0J8U0         | Introduction of autologous pancreatic islet cells into biliary and pancreatic tract, via natural or artificial opening endoscopic                    |
| 3E0J8U1         | Introduction of nonautologous pancreatic islet cells into biliary and pancreatic tract, via natural or artificial opening endoscopic                 |
| XW033DA         | Introduction of donislecel-jujn allogeneic pancreatic islet cellular suspension into peripheral vein, percutaneous approach, new technology group 10 |

The sixth and seventh logic lists are the components of the special logic in MS-DRGs 673, 674, and 675 for pancreatic islet cell transplantation. As discussed in the FY 2005 IPPS/LTCH PPS final rule (69 FR 48950 through 48953), the procedure codes describing islet cell transplantation were added to the GROUPE logic of DRG 315 (Other Kidney and Urinary Tract O.R. Procedures), the predecessor DRG of MS-DRGs 673, 674, and 675, to recognize the resource utilization associated with islet cell transplantation, performed to decrease or eliminate the need for insulin in patients with type 1 diabetes, in the absence of any other surgical procedure.

In the FY 2005 IPPS/LTCH PPS final rule, we acknowledged that islet cell transplants do not involve either the kidney or the urinary tract directly. Rather, the islet cells are transplanted into the patient's liver. We also

acknowledged that the diagnoses are the same for islet cell and pancreas transplants, and that the patient populations involved in these two procedures are virtually identical in terms of comorbidities and the nature of their primary disease. However, we stated islet cell transplants are not exactly the same as solid organ transplants. We stated that while the patient populations requiring intervention are similar, we did not believe that one can equate an operation of the magnitude of a pancreas transplant with a less intensive islet cell transplantation in which the portal vein is accessed and islet cells infused through a catheter. It is only because the technical aspects of islet transplants are of a surgical nature that we modified surgical DRG 315 to reflect the transfusion of islet cells.

To understand the resource use for the subset of cases reporting procedure

codes describing the introduction of pancreatic islet cells for this FY 2027 IPPS/LTCH PPS proposed rule, we began our analysis by examining claims data from the September 2025 update of the FY 2025 MedPAR file for cases assigned to MS-DRGs 673, 674, and 675. We found zero cases reporting procedure codes describing the introduction of pancreatic islet cells in MS-DRGs 673, 674, and 675.

Then, to evaluate the frequency with which the procedure codes describing the introduction of pancreatic islet cells are reported for different clinical scenarios, we examined claims data from the September 2025 update of the FY 2025 MedPAR file to determine the MS-DRGs reporting one of the 11 procedure codes listed previously that describe the introduction of pancreatic islet cells. Our findings are shown in the following table.

| CASES REPORTING ICD-10-PCS PROCEDURE CODES DESCRIBING THE INTRODUCTION OF PANCREATIC ISLET CELLS |                                                                                                                      |                 |                        |               |
|--------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|-----------------|------------------------|---------------|
| MS-DRG                                                                                           | Description                                                                                                          | Number of Cases | Average Length of Stay | Average Costs |
| 003                                                                                              | ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures | 1               | 36                     | \$188,359     |
| 326                                                                                              | Stomach, Esophageal and Duodenal Procedures with MCC                                                                 | 1               | 35                     | \$226,176     |
| 405                                                                                              | Pancreas, Liver and Shunt Procedures with MCC                                                                        | 3               | 30.3                   | \$107,637     |
| 406                                                                                              | Pancreas, Liver and Shunt Procedures with CC                                                                         | 4               | 6.3                    | \$28,268      |
| 650                                                                                              | Kidney Transplant with Hemodialysis with MCC                                                                         | 1               | 15                     | \$160,401     |
| Total                                                                                            |                                                                                                                      | 10              | 20.2                   | \$101,092     |

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The data analysis shows a procedure code describing the introduction of pancreatic islet cells was reported in a total of ten cases across five MS-DRGs with an average length of stay of 20.2 days and average costs of \$101,092. We reviewed these assignments and note that the special logic in MS-DRGs 673, 674, and 675 for pancreatic islet cell transplantation is defined by ICD-10-CM diagnosis codes E10.21 (Type 1 diabetes mellitus with diabetic nephropathy), E10.22 (Type 1 diabetes mellitus with diabetic chronic kidney disease) and E10.29 (Type 1 diabetes mellitus with other diabetic kidney complication). As noted previously, the ICD-10-PCS procedure codes describing the introduction of pancreatic islet cells are all designated as non-O.R. procedures affecting assignment only to MS-DRGs 673, 674, and 675. Therefore, when diagnosis codes E10.21, E10.22, or E10.29 are not reported as principal diagnosis, the MS-DRG assignment is determined by the principal diagnosis and other procedures reported on the claim when the ICD-10-PCS procedure codes describing the introduction of pancreatic islet cells are assigned.

Pancreatic islet cell transplantation is indicated for patients with type 1 diabetes who have attempted to control their hypoglycemic episodes medically but continue to have hypoglycemic episodes without recognizing them.<sup>13</sup> As the indication for pancreatic islet cell transplantation is not limited to

patients with type 1 diabetes mellitus with kidney complications, we believe the special logic in MS-DRGs 673, 674, and 675 for pancreatic islet cell transplantation does not fully reflect the indications for pancreatic islet cell transplantation.

We further note in type 1 diabetes, the body's immune system attacks and destroys the beta cells. Patients with type 1 diabetes must take insulin because their bodies no longer make this hormone. In patients for whom the primary indication for transplantation is unstable glycemic control, particularly hypoglycemic unawareness, the choice is between solid-organ pancreas transplantation alone or islet transplantation.<sup>14</sup> Islet cell transplantation offers a less invasive established alternative to pancreas transplant, and the procedures are regulated similarly.<sup>15</sup> The goal of both pancreas whole organ transplant and islet cell transplantation is to enable effective, stable glycemic management (often with insulin independence), to improve quality of life, and to reduce secondary complications. Both pancreas and islet cell transplantation require lifelong immunosuppression to prevent rejection of the graft. Islet transplantation may be performed at the same time as or after a kidney transplant. Kidney transplant recipients will already be taking immunosuppressants to prevent rejection of the transplanted kidney. Therefore, the islet transplant does not add much more risk.

As discussed in prior rulemaking, the MS-DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. We generally seek to identify sufficient sets of claims data with demonstrated clinical similarity in developing diagnosis related groups. After reviewing the indications for both whole organ pancreas transplant and pancreatic islet cell transplantation, and consideration of the intent of the MS-DRGs, we believe that for clinical coherence, the cases reporting procedure codes that describe the introduction of pancreatic islet cells should be grouped with the subset of cases that report pancreas transplant procedures. While we continue to acknowledge that islet cell transplants are not exactly the same as solid organ pancreas transplants, we believe the procedures are coherent given the similarity in clinical indication. For these reasons, we believe reassigning the 11 ICD-10-PCS procedure codes that describe the introduction of pancreatic islet cells from MS-DRGs 673, 674, and 675 to Pre-MDC MS-DRGs 008 (Simultaneous Pancreas and Kidney Transplant), MS-DRG 010 (Pancreas Transplant) and MS-DRG 019 (Simultaneous Pancreas and Kidney Transplant with Hemodialysis) would improve clinical coherence in these MS-DRGs.

The following table reflects the simulation of our proposed changes in MS-DRGs 008, 010, and 019.

| MS-DRG |                                                                                              | Number of Cases | Average Length of Stay | Average Cost    |
|--------|----------------------------------------------------------------------------------------------|-----------------|------------------------|-----------------|
| 008    | All Cases                                                                                    | 168             | 9.3                    | \$51,760        |
|        | -- add cases reporting procedure codes describing the introduction of pancreatic islet cells | 0               | 0                      | \$0             |
|        | <b>Simultaneous Pancreas, Islet Cell and Kidney Transplant</b>                               | <b>168</b>      | <b>9.3</b>             | <b>\$51,760</b> |
| 010    | All Cases                                                                                    | 20              | 15.8                   | \$66,872        |
|        | -- add cases reporting procedure codes describing the introduction of pancreatic islet cells | 8               | 18.9                   | \$82,770        |
|        | <b>Pancreas or Islet Cell Transplant</b>                                                     | <b>28</b>       | <b>16.7</b>            | <b>\$71,414</b> |
| 019    | All Cases                                                                                    | 56              | 14.5                   | \$69,841        |
|        | -- add cases reporting procedure codes describing the introduction of pancreatic islet cells | 1               | 15                     | \$160,401       |
|        | <b>Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis</b>             | <b>57</b>       | <b>14.5</b>            | <b>\$71,430</b> |

We believe that this simulation supports that the resulting MS-DRG assignments would be more clinically

homogeneous, coherent and better reflect hospital resource use. As the table shows, for MS-DRG 008, there

were a total of 168 cases with an average length of stay of 9.3 days and average costs of \$51,760. For MS-DRG 010,

<sup>13</sup> Spence KT, Ladie DE. Islets Transplantation. [Updated 2023 Aug 8]. In: StatPearls [internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK562272/>.

<sup>14</sup> Mittal S, Johnson P, Friend P. Pancreas transplantation: solid organ and islet. Cold Spring Harb Perspect Med. 2014 Apr 1;4(4):a015610. doi: 10.1101/cshperspect.a015610. PMID: 24616200; PMCID: PMC3968790.

<sup>15</sup> Rickels MR, Robertson RP. Pancreatic Islet Transplantation in Humans: Recent Progress and Future Directions. Endocr Rev. 2019 Apr 1;40(2):631-668. doi: 10.1210/er.2018-00154. PMID: 30541144; PMCID: PMC6424003.



there were a total of 20 cases with an average length of stay of 15.8 days and average costs of \$66,872. For MS-DRG 019, there were a total of 56 cases with an average length of stay of 14.5 days and average costs of \$69,841. A review of this simulation shows that adding a new “Islet Cell Transplant Procedures” logic list, to the Grouper logic in MS-DRGs 008, 010, and 019 has a limited effect on the average costs of these MS-DRGs, while leading to a grouping that is more coherent and better reflects the clinical severity and resource use involved in these cases.

In summary, for FY 2027, for clinical coherence, we are proposing to add the 11 ICD-10-PCS procedure codes that describe the introduction of pancreatic islet cells to a new “Islet Cell Transplant Procedures” logic list in MS-DRGs 008, 010, and 019. Additionally, we are also proposing to delete the sixth logic list entitled “or Principal Diagnosis” that is defined by ICD-10-CM diagnosis codes E10.21 (Type 1 diabetes mellitus with diabetic nephropathy), E10.22 (Type 1 diabetes mellitus with diabetic chronic kidney disease) and E10.29 (Type 1 diabetes mellitus with other diabetic kidney complication) and the seventh logic list entitled “and Non-Operating Room Procedures” from MS-DRGs 673, 674, and 675. Lastly, for consistency, we are proposing to change the title of MS-DRG 008 from “Simultaneous Pancreas and Kidney Transplant” to “Simultaneous Pancreas, Islet Cell and Kidney Transplant,” proposing to change the title of MS-DRG 010 from

“Pancreas Transplant” to “Pancreas or Islet Cell Transplant” and proposing to change the title of MS-DRG 019 from “Simultaneous Pancreas and Kidney Transplant with Hemodialysis” to “Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis” to better reflect the assigned procedures effective October 1, 2026, for FY 2027. Under this proposal, the current “principal or secondary diagnosis” logic in MS-DRGs 008, 010, and 019 would be maintained. Additionally, to maintain stability, we propose to add logic to MS-DRG 010 to exclude cases also reporting kidney transplant procedures to ensure cases will continue to group accordingly to MS-DRGs 008 and 019.

We refer the reader to Table 6P.4a, Table 6P.4b, and Table 6P.4c associated with this FY 2027 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index>) for the list of procedure codes we are proposing to define in the “Islet Cell Transplant Procedures” logic list in Pre-MDC MS-DRGs 008, 010, and 019. We note that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule.

**7. MDC 12 (Diseases and Disorders of the Male Reproductive System): Prostatectomy**

Consistent with our annual review of the MS-DRGs, we identified that the

current Grouper logic for MDC 12 MS-DRGs 707 and 708 (Major Male Pelvic Procedures with MCC and without CC/MCC, respectively) contains a logic list referred to as “OPERATING ROOM PROCEDURES” that includes 51 procedure codes describing various male pelvic procedures, including procedure codes describing the destruction, or resection of the prostate, and also includes eight procedure code combinations or procedure code “clusters” that, when reported together, satisfy the logic for assignment to MS-DRGs 707 and 708. The code combinations are represented by two procedure codes and include one code for the resection of the prostate with one code for the resection of bilateral seminal vesicles.

We refer the reader to the ICD-10 MS-DRG Definitions Manual Version 43.1, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>, for complete documentation of the Grouper logic for MDC 12 MS-DRGs 707 and 708.

The eight ICD-10-PCS procedure code combinations currently assigned to MS-DRGs 707 and 708 that identify the resection of the prostate with the resection of bilateral seminal vesicles are shown in the following table:

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| ICD-10-PCS Code     | Description                                                               |
|---------------------|---------------------------------------------------------------------------|
| 0VT00ZZ and 0VT30ZZ | Resection of prostate, open approach                                      |
|                     | Resection of bilateral seminal vesicles, open approach                    |
| 0VT00ZZ and 0VT34ZZ | Resection of prostate, open approach                                      |
|                     | Resection of bilateral seminal vesicles, percutaneous endoscopic approach |
| 0VT04ZZ and 0VT30ZZ | Resection of prostate, percutaneous endoscopic approach                   |
|                     | Resection of bilateral seminal vesicles, open approach                    |
| 0VT04ZZ and 0VT34ZZ | Resection of prostate, percutaneous endoscopic approach                   |
|                     | Resection of bilateral seminal vesicles, percutaneous endoscopic approach |
| 0VT07ZZ and 0VT30ZZ | Resection of prostate, via natural or artificial opening                  |
|                     | Resection of bilateral seminal vesicles, open approach                    |
| 0VT07ZZ and 0VT34ZZ | Resection of prostate, via natural or artificial opening                  |
|                     | Resection of bilateral seminal vesicles, percutaneous endoscopic approach |
| 0VT08ZZ and 0VT30ZZ | Resection of prostate, via natural or artificial opening endoscopic       |
|                     | Resection of bilateral seminal vesicles, open approach                    |
| 0VT08ZZ and 0VT34ZZ | Resection of prostate, via natural or artificial opening endoscopic       |
|                     | Resection of bilateral seminal vesicles, percutaneous endoscopic approach |

As we examined the Grouper logic that would determine an assignment of a case to MDC 12 MS-DRGs 707 and

708, we noted that ICD-10-PCS codes 0VT00ZZ (Resection of prostate, open approach) and 0VT04ZZ (Resection of

prostate, percutaneous endoscopic approach) that describe the resection of the prostate, differing only in approach,

are assigned to MS-DRGs 707 and 708 as standalone procedures, as well as being included in one of the eight procedure code combinations, or code clusters, listed previously in these same MS-DRGs. We note that the Grouper software program will recognize codes 0VT00ZZ and 0VT04ZZ and assign MS-DRGs 707 and 708 even when a procedure code describing the resection of the bilateral seminal vesicles is not also reported when the other parameters of the Grouper logic are met. As procedure codes 0VT00ZZ and 0VT04ZZ are assigned to MS-DRGs 707 and 708 as standalone procedures, specific assignment of these procedure codes in procedure code combinations

in MS-DRGs 707 and 708 is not required.

During our review of this issue, we noted that that ICD-10-PCS codes 0VT07ZZ (Resection of prostate, via natural or artificial opening) and 0VT08ZZ (Resection of prostate, via natural or artificial opening endoscopic) that describe the transurethral resection of the prostate, or removal of the prostate using an instrument inserted through the urethra, are also represented in the eight procedure code combinations in MS-DRGs 707 and 708. These codes are assigned to MDC 12 MS-DRGs 713 and 714 (Transurethral Prostatectomy with CC/MCC and without CC/MCC) when reported as standalone procedures. We refer the reader to the ICD-10 MS-DRG

Definitions Manual Version 43.1, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>, for complete documentation of the Grouper logic for MDC 12 MS-DRGs 713 and 714.

We then analyzed claims data from the September 2025 update of the September 2025 MedPAR file for all cases in MS-DRGs 707 and 708 and compared the results to cases reporting procedure codes describing transurethral prostatectomy and resection of bilateral seminal vesicles in these MS-DRGs. Our findings are shown in the following table.

| <b>MS-DRGS 707-708: ALL CASES AND CASES REPORTING PROCEDURE CODES DESCRIBING TRANSURETHRAL PROSTATECTOMY AND RESECTION OF BILATERAL SEMINAL VESICLES</b> |                        |                               |                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|-------------------------------|----------------------|
| <b>MS-DRG</b>                                                                                                                                            | <b>Number of Cases</b> | <b>Average Length of Stay</b> | <b>Average Costs</b> |
| MS-DRG 707--All cases                                                                                                                                    | 1,697                  | 3.1                           | \$19,942             |
| MS-DRG 707--Cases reporting procedure codes describing transurethral prostatectomy and resection of bilateral seminal vesicles                           | 3                      | 4                             | \$14,896             |
| MS-DRG 708--All cases                                                                                                                                    | 1,685                  | 1.5                           | \$14,075             |
| MS-DRG 708--Cases reporting procedure codes describing transurethral prostatectomy and resection of bilateral seminal vesicles                           | 1                      | 1                             | \$6,726              |

As shown in the table, for MS-DRG 707, we identified a total of 1,697 cases, with an average length of stay of 3.1 days and average costs of \$19,942. Of the 1,697 cases in MS-DRG 707, there were three cases reporting transurethral prostatectomy and resection of bilateral seminal vesicles with an average length

of stay of 4 days and average costs of \$14,896. For MS-DRG 708, we identified a total of 1,685 cases, with an average length of stay of 1.5 days and average costs of \$14,075. Of the 1,685 cases in MS-DRG 708, there was one case reporting transurethral prostatectomy and resection of bilateral

seminal vesicles with a length of stay of 1 day and costs of \$6,726.

We also examined claims data from the September 2025 update of the September 2025 MedPAR file for MS-DRGs 713 and 714. Our findings are shown in the following table.

| <b>MS-DRG</b> | <b>Number of Cases</b> | <b>Average Length of Stay</b> | <b>Average Costs</b> |
|---------------|------------------------|-------------------------------|----------------------|
| 713           | 3,746                  | 3.4                           | \$14,670             |
| 714           | 860                    | 1.7                           | \$10,869             |

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In MS-DRG 713, we found a total of 3,746 cases with an average length of stay of 3.4 days and average costs of \$14,670. In MS-DRG 714, we found a total of 860 cases with an average length of stay of 1.7 days and average costs of \$10,869.

Overall, the data analysis shows that the average costs for the cases reporting transurethral prostatectomy and resection of bilateral seminal vesicles in MS-DRGs 707 and 708 are more aligned with the average costs for all the cases in MS-DRGs 713 (\$14,896 versus \$14,670) and 714 (\$6,726 versus \$10,869), respectively.

We reviewed this issue and noted that ICD-10-PCS procedure codes 0VT07ZZ

or 0VT08ZZ describe transurethral resection of the prostate, and therefore, are most clinically aligned with the procedure codes assigned to MDC 12 MS-DRGs 713 and 714, where they are currently assigned when reported as standalone procedures.

Therefore, for FY 2027, we are proposing to delete the eight ICD-10-PCS procedure code combinations listed previously from the Grouper logic of MDC 12 MS-DRGs 707 and 708 (Major Male Pelvic Procedures with CC/MCC and without CC/MCC, respectively). Under this proposal, when the other parameters of the Grouper logic are met, cases reporting procedure codes 0VT00ZZ (Resection of prostate, open

approach) and 0VT04ZZ (Resection of prostate, percutaneous endoscopic approach) would group to MS-DRGs 707 and 708, even when a procedure code describing the resection of the bilateral seminal vesicles is not also reported. Additionally, under this proposal, when the other parameters of the Grouper logic are met, cases reporting procedure codes 0VT07ZZ (Resection of prostate, via natural or artificial opening) or 0VT08ZZ (Resection of prostate, via natural or artificial opening endoscopic) would group to MS-DRGs 713 and 714 (Transurethral Prostatectomy with CC/MCC and without CC/MCC), even when a procedure code describing the

resection of the bilateral seminal vesicles is not also reported.

During our review of this issue and the examination of the MS-DRGs within MDC 12, we noted that the title of MS-DRGs 715 and 716 is “Other Male Reproductive System O.R. Procedures for Malignancy with and without CC/MCC, respectively” and the title of MS-DRGs 717 and 718 is “Other Male Reproductive System O.R. Procedures Except Malignancy with and without CC/MCC, respectively.” In examining the GROUPER logic for these MS-DRGs and reviewing the diagnoses listed under the heading of “Principal Diagnosis” in the ICD-10 MS-DRG Definitions Manual, we believe the titles for these MS-DRGs no longer accurately reflect the assigned diagnoses. The titles of DRGs 715, 716, 717, and 718 were established prior to the transition to the Medicare Severity DRGs (MS-DRGs) from the CMS DRGs (48 FR 39883). In the development of the DRGs, generally, in each MDC, a medical and a surgical class was formed and referred to as “other medical diseases” and “other surgical procedures,” respectively. The “other” medical and surgical classes are not as precisely defined from a clinical perspective and include diagnoses or procedures which are infrequently encountered. The “other” surgical class contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC. Assignment to the “other” surgical class should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate. As the cases in MS-DRGs 715 and 716 are further defined based on the precise principal diagnosis for which the patients were admitted to the hospital, we believe it is appropriate to propose to revise the titles of these MS-DRGs for consistency. Therefore, we are also proposing to change the title of MS-DRGs 715 and 716 from “Other Male Reproductive System O.R. Procedures for Malignancy with and without CC/MCC, respectively” to “Male Reproductive System and Other O.R. Procedures for Malignancy with and without CC/MCC, respectively” and to change the title of MS-DRGs 717 and 718 from “Other Male Reproductive System O.R. Procedures Except Malignancy with and without CC/MCC, respectively” to “Other Male Reproductive System O.R. Procedures with and without CC/MCC, respectively” to better reflect the assigned diagnoses.

As discussed in section II.C.1.b of the preamble of this proposed rule, we are providing a test version of the ICD-10

MS-DRG GROUPER Software, Version 44, so that the public can better analyze and understand the impact of the proposals included in this proposed rule. We note that at the time of the development of the test software, this issue was unable to be addressed and therefore, the test software does not reflect the proposed change to the title of MS-DRGs 715 and 716 from “Other Male Reproductive System O.R. Procedures for Malignancy with and without CC/MCC, respectively” to “Male Reproductive System and Other O.R. Procedures for Malignancy with and without CC/MCC, respectively” and the proposed change to the title of MS-DRGs 717 and 718 from “Other Male Reproductive System O.R. Procedures Except Malignancy with and without CC/MCC, respectively” to “Other Male Reproductive System O.R. Procedures with and without CC/MCC, respectively” in MDC 12 for Version 44.

8. MDC 13 (Diseases and Disorders of the Female Reproductive System): Fluorescence Guided Procedures of the Female Reproductive System Using Pafolacianine

CYTALUX® (pafolacianine) is a folate receptor-targeted fluorescent optical imaging agent used as an adjunct for intraoperative identification of ovarian cancer. CYTALUX® binds to the folate receptors on these cancer cells and is endocytosed into folate receptor positive cancer cells. CYTALUX® is administered intravenously prior to gynecologic oncology procedures, including ovarian cytoreduction and debulking surgeries, and requires use of a near-infrared imaging system (NIR) to illuminate, thereby making cancer visible within the surgical field. CYTALUX® received FDA approval and is indicated as an adjunct for intraoperative identification of malignant lesions in adult patients with ovarian cancer. We note that CYTALUX® for the ovarian indication was approved for new technology add-on payments for FY 2024 (88 FR 58804 through 58810) and FY 2025 (89 FR 69120 through 69126).

We received a request from the manufacturer of CYTALUX® to modify the GROUPER logic of MS-DRGs 736, 737, and 738 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with an ICD-10-PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) to the higher severity level MS-DRG 736 (with MCC) or MS-DRG 737 (with CC). According to the

requestor, the utilization of CYTALUX® does not change the surgical procedure but adds significant cost. The requestor performed their own analysis of Medicare claims data from 10/1/2023–3/31/2025 and stated they found approximately 13 cases that used CYTALUX® in ovarian surgery and that they expect adoption to accelerate as NIR systems become more widely available. The requestor stated they found that over 50% of cases using CYTALUX® in ovarian procedures triggered new technology add-on payments averaging \$2,285. The requestor also stated they found cases reporting an ICD-10-PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) within MS-DRG 737 exhibit higher average costs than baseline and align more closely with cases in MS-DRG 736. Additionally, the requestor stated their analysis also found cases that reported the use of CYTALUX® in MS-DRGs 739, 740, and 741 (Uterine and Adnexa Procedures for Non-Ovarian and Non-Adnexal Malignancy with MCC, with CC, and without CC/MCC, respectively) due to the reporting of diagnosis codes describing metastatic malignancies. The requestor stated their analysis found that cases reporting an ICD-10-PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) cases in MS-DRG 737 exhibited higher average costs than baseline (\$34,735 vs. \$23,538) and aligned more closely with cases in MS-DRG 736 (\$39,682).

The requestor further asserted that their review of the Inpatient Standard Analytical Files (SAF) indicated there were some accounts underreporting the full cost of the vial of CYTALUX® due to inconsistent guidance for single-use inpatient drugs and that, where applicable, pharmacy costs were adjusted to account for missing costs of the single-use vial. The requestor stated they found that cases reporting an ICD-10-PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) in MS-DRG 737 were approximately \$11,000 more expensive than non-CYTALUX cases when controlled for the underreporting of costs. Therefore, the requestor suggested that CMS reassign cases with an ICD-10-PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) to MS-DRGs 736 or 737 to ensure accurate payment, clinical

integrity, and to prevent barriers to hospital adoption of CYTALUX® as NIR system availability expands nationwide.

To begin our analysis, we reviewed the Grouper logic for MS-DRGs 736, 737, 738, 739, 740, and 741. MS-DRGs 736, 737, 738, 739, 740 and 741 contains a logic list referred to as “OPERATING ROOM PROCEDURES” that includes 689 ICD-10-PCS procedure codes that describe uterine and adnexa procedures, a logic list referred to as “Ovarian or Adnexal Malignancy PRINCIPAL

DIAGNOSIS” that includes 22 ICD-10-CM diagnosis codes that describe ovarian or adnexal malignancies and a logic list referred to as “Non-Ovarian and Non-Adnexal Malignancy PRINCIPAL DIAGNOSIS” that includes 36 ICD-10-CM diagnosis codes that describe non-ovarian and non-adnexal malignancies. We refer the reader to the ICD-10 MS-DRG Definitions Manual, Version 43.1 (available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective->

*payment-systems/acute-inpatient-pps/ms-drug-classifications-and-software*) for complete documentation of the Grouper logic for MS-DRGs 736, 737, 738, 739, 740, and 741.

The following five ICD-10-PCS procedure codes describe fluorescence guided procedures of the female reproductive system using pafolacianine for the ovarian indication.

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| ICD-10-PCS Code | Description                                                                                                                   |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------|
| 8E0U0EN         | Fluorescence guided procedure of female reproductive system using pafolacianine, open approach                                |
| 8E0U3EN         | Fluorescence guided procedure of female reproductive system using pafolacianine, percutaneous approach                        |
| 8E0U4EN         | Fluorescence guided procedure of female reproductive system using pafolacianine, percutaneous endoscopic approach             |
| 8E0U7EN         | Fluorescence guided procedure of female reproductive system using pafolacianine, via natural or artificial opening            |
| 8E0U8EN         | Fluorescence guided procedure of female reproductive system using pafolacianine, via natural or artificial opening endoscopic |

In the ICD-10 MS-DRGs Definitions Manual Version 43.1, procedure codes 8E0U0EN, 8E0U3EN, 8E0U4EN, 8E0U7EN, and 8E0U8EN are designated as non-O.R. procedures for purposes of MS-DRG assignment, therefore when CYTALUX® is utilized during a uterine and adnexa procedure described by one of the 689 ICD-10-PCS procedure codes

in the Grouper logic for MS-DRGs 736, 737, 738, 739, 740, and 741, the ICD-10-PCS code describing the uterine and adnexa procedure will determine the surgical MS-DRG assignment to one of the previously listed surgical MS-DRGs based on the principal diagnosis reported.

We then examined claims data from the September 2025 update of the FY

2025 MedPAR file for MS-DRGs 736, 737, 738, 739, 740, and 741 to identify cases reporting one of the five procedure codes listed previously that describe fluorescence guided surgery using CYTALUX® (pafolacianine). Our findings are shown in the following table:

| MS-DRGS 736, 737, 738, 739, 740 AND 741: ALL CASES AND CASES REPORTING PROCEDURE CODES THAT DESCRIBE FLUORESCENCE GUIDED SURGERY USING CYTALUX® (PAFOLACIANINE) |                                                                                                     |                 |                        |               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|-----------------|------------------------|---------------|
| MS-DRG                                                                                                                                                          |                                                                                                     | Number of Cases | Average Length of Stay | Average Costs |
| 736                                                                                                                                                             | All cases                                                                                           | 647             | 8.5                    | \$33,196      |
|                                                                                                                                                                 | Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) | 2               | 7                      | \$28,068      |
| 737                                                                                                                                                             | All cases                                                                                           | 1,803           | 4.3                    | \$18,702      |
|                                                                                                                                                                 | Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) | 0               | 0                      | \$0           |
| 738                                                                                                                                                             | All Cases                                                                                           | 317             | 2.5                    | \$13,519      |
|                                                                                                                                                                 | Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) | 0               | 0                      | \$0           |
| 739                                                                                                                                                             | All cases                                                                                           | 481             | 8.4                    | \$33,235      |
|                                                                                                                                                                 | Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) | 2               | 1.5                    | \$11,565      |
| 740                                                                                                                                                             | All cases                                                                                           | 1,327           | 3.2                    | \$16,784      |
|                                                                                                                                                                 | Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) | 1               | 5                      | \$39,154      |
| 741                                                                                                                                                             | All Cases                                                                                           | 740             | 1.7                    | \$13,365      |
|                                                                                                                                                                 | Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) | 1               | 1                      | \$14,036      |

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As shown in the table, in MS-DRG 736, we identified a total of 647 cases with an average length of stay of 8.5 days and average costs of \$33,196. Of those 647 cases, there were two cases reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with average costs lower than the average costs in the FY 2025 MedPAR file for MS-DRG 736 (\$28,068 compared to \$33,196) and a shorter average length of stay (7 days compared to 8.5 days). There were zero cases reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) in MS-DRGs 737 and 738.

In MS-DRG 739, we identified a total of 481 cases with an average length of stay of 8.4 days and average costs of \$33,235. Of those 481 cases, there were two cases reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with average costs lower than the average costs in the FY 2025 MedPAR file for MS-DRG 739 (\$11,565 compared to \$33,235) and a shorter average length of stay (1.5 days compared to 8.4 days). In MS-DRG 740, we identified a total of 1,327 cases with an average length of stay of 3.2 days and average costs of \$16,784. Of those 1,327 cases, there was one case reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with costs higher than the average costs in the FY 2025 MedPAR file for MS-DRG 740 (\$39,154 compared to \$16,784), and a longer length of stay (5 days compared to 3.2 days). In MS-DRG 741, we identified a total of 740 cases with an average length of stay of 1.7 days and average costs of \$13,365. Of those 1,327 cases, there was one case reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with costs higher than the average costs in the FY 2025 MedPAR file for MS-DRG 741 (\$14,036 compared to \$13,365), and a shorter length of stay (1 day compared to 1.7 days).

The data reflects the six cases reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) found across MS-DRGs 736, 737, 738, 739, 740, and 741 have an average length of stay of 3.8 days and average costs of \$22,076. These six cases have a shorter average length of stay (3.8 days versus 8.5 days) and lower average costs (\$22,076 versus \$33,196) when

compared to all the cases in MS-DRG 736. The six cases reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) found across MS-DRGs 736, 737, 738, 739, 740, and 741 have a shorter average length of stay (3.8 days versus 4.3 days) and higher average costs (\$22,076 versus \$18,702) when compared to all the cases in MS-DRG 737.

After reviewing the claims data, we believe it is premature to consider a proposal for cases with an ICD-10-PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) for FY 2027. While the data analysis reflects that six cases that report one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) across MS-DRGs 736, 737, 738, 739, 740, and 741 demonstrate slightly higher average costs compared to all the cases in MS-DRG 737, the number of cases is small across the MS-DRGs. The claims data also reflect a wide variance with regard to the average costs for these cases reporting fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine). We note the one case that reported a fluorescence guided procedure of the female reproductive system using CYTALUX® (pafolacianine) in MS-DRG 740 had a length of stay of 5 days and costs of \$39,154, while the two cases that reported a procedure code describing a fluorescence guided procedure of the female reproductive system using CYTALUX® (pafolacianine) in MS-DRG 739 had an average length of stay of 1.5 days and average costs of \$11,565.

We cannot ascertain from the claims data the resource use specifically attributable to the utilization of fluorescence guidance using CYTALUX® (pafolacianine) in procedures of the female reproductive system during inpatient admissions. We recognize the average costs of the small numbers of cases reporting an ICD-10-PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) can be greater when compared to the average costs of all cases in their respective MS-DRG however, the MS-DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We further note that section 1886(d)(5)(A) of the Act provides for Medicare payments to

Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs. We believe it would be advantageous to allow for more claims data to be analyzed in consideration of any future modifications to the MS-DRGs for which fluorescence guided surgeries using CYTALUX® (pafolacianine) are assigned. We will continue to evaluate the clinical coherence and resource consumption costs that impact this subset of cases and their MS-DRG assignment.

Therefore for the reasons stated, for FY 2027, we are not proposing to modify the GROUPER logic of MS-DRGs 736, 737, and 738 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC, with CC, and without CC/MCC, respectively) by reassigning cases reporting ICD-10-PCS codes that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) to the higher severity level MS-DRG 736 (with MCC) or MS-DRG 737 (with CC).

During our review of this issue, we noted that the data analysis reflects that in cases reporting uterine and adnexa procedures in MS-DRGs 736, 737, 738, 739, 740, and 741, the average costs and length of stay are generally similar without regard to the presence of diagnosis codes describing “ovarian or adnexal” malignancies or “non-ovarian or non-adnexal” malignancies. In MS-DRG 736, there were 647 cases reporting an uterine and adnexa procedures with a principal diagnosis describing an “ovarian or adnexal” malignancy and a MCC with average costs of \$33,196 and an average length of stay of 8.5 days compared to 481 cases reporting an uterine and adnexa procedures with a principal diagnosis describing a “non-ovarian or non-adnexal” malignancy and a MCC with average costs of \$33,235 and an average length of stay of 8.4 days in MS-DRG 739. In MS-DRG 737, there were 1,803 cases reporting an uterine and adnexa procedures with a principal diagnosis describing an “ovarian or adnexal” malignancy and a CC with average costs of \$18,702 and an average length of stay of 4.3 days compared to 1,327 cases reporting an uterine and adnexa procedures with a principal diagnosis describing a “non-ovarian or non-adnexal” malignancy and a CC with average costs of \$16,784 and an average length of stay of 3.2 days in MS-DRG 740. In MS-DRG 738, there were 317 cases reporting an uterine and adnexa procedures with a principal diagnosis describing an “ovarian or adnexal” malignancy without a CC or an

MCC with average costs of \$13,519 and an average length of stay of 2.5 days compared to 740 cases reporting an uterine and adnexa procedures with a principal diagnosis describing a “non-ovarian or non-adnexal” malignancy without a CC or an MCC with average costs of \$13,365 and an average length of stay of 1.7 days in MS–DRG 741.

We reviewed these findings and believe that it may no longer be necessary to subdivide these MS–DRGs based on the diagnosis codes reported. In the FY 1987 proposed notice titled “Medicare Program; Changes to the DRG Classification System” (51 FR 8770 through 8771), we stated that our analysis of cases with a principal diagnosis of malignancy where both a hysterectomy and uterine or adnexa procedures were performed suggested that malignancies and non-malignancies should be classified in different DRGs, and that ovarian and adnexa cancers were the most resource intensive of the malignancies in the DRGs reviewed. We further stated that, among the cases examined in the DRGs, the diagnosis had consistently greater explanatory power with respect to resource intensity than did the procedure performed, therefore we stated that cases with a principal diagnosis of malignancy would be further subdivided. Therefore, for FY 1987, DRG 357 (Non-Radical Hysterectomy, Uterus and Adnexa Procedures, for Ovarian and Adnexal Malignancy) and DRGs 354 and 355 (Non-Radical Hysterectomy, Uterus and

Adnexa Procedures for Malignancy Except Ovarian/Adnexal Malignancy; Age over 69 and/or C.C., and Age under 70 without C.C., respectively) were created to “increase homogeneity and thus more accurately reflect resource intensity of cases assigned to these DRGs” (51 FR 31571).

Our analysis of claims data from the September 2025 update of the FY 2025 MedPAR file shows that in the 39 years since the DRGs for cases reporting uterine and adnexa procedures split based on the presence of diagnosis codes describing “ovarian or adnexal” malignancies or “non-ovarian or non-adnexal” malignancies were created, the resource utilization appears to now be more related to the procedures performed rather than the diagnoses describing malignancies reported on the claim, and therefore we believe it is appropriate to restructure these MS–DRGs accordingly. In our direct comparison of the cases reporting diagnosis codes describing “ovarian or adnexal” malignancies or “non-ovarian or non-adnexal” malignancies in these MS–DRGs, we believe the distinction is no longer meaningful with regard to resource consumption. Clinically, a principal diagnosis of an “ovarian or adnexal” or a “non-ovarian or non-adnexal” malignancy in association with a uterine and adnexa procedure requires a commensurate level of patient care, including managing pain, monitoring for complications, ensuring proper wound and drain care,

preventing blood clots, managing bowel function, and facilitating recovery through gradual activity, diet, and mobility. Decisions on potential further treatment like chemotherapy or radiation therapy for these diagnoses are based on the cancer’s stage.

We note that, as discussed in prior rulemaking, the MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. We generally seek to identify sufficient sets of claims data with demonstrated clinical similarity in developing diagnosis related groups. As a result of our analysis and review of this issue, and consideration of the intent of the MS–DRGs, we believe the findings support restructuring the six MS–DRGs by proposing to create new MS–DRGs for uterine and adnexa procedures for female reproductive system malignancies and eliminating the logic that differentiates cases by reporting principal diagnoses describing “ovarian or adnexal” and “non-ovarian or non-adnexal” malignancies.

For these reasons, we are proposing the deletion of MS–DRGs 736, 737, 738, 739, 740, and 741, and the creation of a base MS–DRG for cases reporting uterine and adnexa procedures and a principal diagnosis describing a female reproductive system malignancy, split by a three-way severity level subgroup. The following table illustrates our simulation of the proposal.

| Proposed new MS-DRG                                                  | Number of Cases | Average Length of Stay | Average Costs |
|----------------------------------------------------------------------|-----------------|------------------------|---------------|
| Proposed new MS-DRG XXX Uterine and Adnexa Procedures for Malignancy | 5,315           | 4.4                    | \$20,251      |

Consistent with our established process as discussed in section II.C.1.b. of the preamble of this proposed rule, once the decision has been made to propose to make further modifications to the MS–DRGs, all five criteria to

create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the preamble of this

FY 2027 IPPS/LTCH PPS proposed rule. We note that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG was met. The following table illustrates our findings.

| Proposed new MS-DRGs | Number of Cases | Average Length of Stay | Average Costs |
|----------------------|-----------------|------------------------|---------------|
| With MCC             | 1,128           | 8.5                    | \$33,213      |
| With CC              | 3,130           | 3.8                    | \$17,889      |
| Without CC/MCC       | 1,057           | 1.9                    | \$13,411      |

For the proposed new MS–DRGs, there is (1) at least 500 cases in the MCC subgroup, the CC subgroup, and in the without CC/MCC subgroup; (2) at least 5 percent of the cases are in the MCC subgroup, the CC subgroup, and in the without CC/MCC subgroup; (3) at least a 20 percent difference in average costs

between the MCC subgroup and the CC subgroup and between the CC group and NonCC subgroup; (4) at least a \$2,000 difference in average costs between the MCC subgroup and the with CC subgroup and between the CC subgroup and NonCC subgroup; and (5) at least a 3-percent reduction in cost variance,

indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

Therefore, for FY 2027, we are proposing to delete MS-DRGs 736, 737, 738, 739, 740, and 741 and proposing to create new MS-DRGs 731 (Uterine and Adnexa Procedures for Malignancy with MCC), MS-DRG 732 (Uterine and Adnexa Procedures for Malignancy with CC), and MS-DRG 733 (Uterine and Adnexa Procedures for Malignancy without CC/MCC). We are proposing to include the current list of 689 ICD-10-PCS procedure codes in the logic for MS-DRGs 736, 737, 738, 739, 740, and 741 for case assignment of uterine and adnexa procedures for the proposed new MS-DRGs. We refer the reader to Table 6P.5a and Table 6P.5b associated with this FY 2027 IPPS/LTCH PPS proposed rule (which are available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps>) for the lists of the 58 diagnosis codes and 689 procedure codes we are proposing to define in the logic for the proposed new MS-DRGs. We note that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule.

#### 9. MDC 25 (Human Immunodeficiency Virus Infections): Significant HIV Related Conditions

Under the ICD-10 IPPS MS-DRGs, each of the 25 MDCs generally reflect a major organ system or etiology. Within each MDC, there is a list of all the possible ICD-10-CM diagnoses or conditions that correspond to the specific organ system(s) or etiology reflected by the respective MDC title to ensure clinical coherence. When one of the listed conditions for a designated MDC is reported as a principal or secondary diagnosis, the ICD-10-CM diagnosis code informs the resulting MS-DRG assignment from within that MDC.

The logic for case assignment under MDC 25 (Human Immunodeficiency Virus Infections) is comprised of ICD-10-CM diagnosis code B20 (Human immunodeficiency virus [HIV] disease) when reported as a principal diagnosis or when reported as a secondary diagnosis with a principal diagnosis of a significant HIV related condition and the logic for case assignment specifically to MS-DRGs 974, 975, and 976 (HIV with Major Related Condition with MCC, with CC, without CC/MCC, respectively) under MDC 25 is comprised of ICD-10-CM diagnosis code B20 when reported as a principal or secondary diagnosis with a principal or secondary diagnosis of a major related condition as displayed in the

ICD-10 MS-DRG Definitions Manual, Version 43.1 (available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>). In reviewing the listed diagnoses that fall under the MDC 25 header “AND PRINCIPAL DIAGNOSIS OF SIGNIFICANT HIV RELATED CONDITION” as reflected in the ICD-10 MS-DRG Definitions Manual, Version 43.1, we identified that a number of the listed diagnoses under this specific header overlap with the listed diagnoses in the logic list for case assignment to MS-DRGs 974, 975, and 976 as a major related condition of HIV, as displayed in the ICD-10 MS-DRG Definitions Manual, Version 43.1. To improve clarity of the listed diagnoses between the header that reflects “SIGNIFICANT” and the diagnoses listed in the logic for case assignment to MS-DRGs 974, 975, and 976 described as “Major”, we believe the term “SIGNIFICANT” should be removed from the header under MDC 25.

We also identified a subset of diagnoses listed under the header “AND PRINCIPAL DIAGNOSIS OF SIGNIFICANT HIV RELATED CONDITION” that do not appear to describe a significant HIV related condition. For example, ICD-10-CM diagnosis code A09 Infectious gastroenteritis and colitis, unspecified, and ICD-10-CM diagnosis code A74.9 Chlamydial infection, unspecified, are listed under the current significant HIV header list of diagnoses; however, these same diagnoses are not listed as a major condition under MS-DRG 974, 975, and 976. We do not believe these conditions are clinically appropriate to be included as a significant HIV related condition. We intend to perform additional review and analysis of the diagnoses listed in the logic for case assignment to MDC 25 as well as specifically, the logic for case assignment to MS-DRGs 974, 975, and 976 in consideration of any potential modifications that may be warranted. Any discussion regarding proposed changes will be discussed in future rulemaking.

Therefore, for FY 2027, we are proposing to remove the term “SIGNIFICANT” under the header for MDC 25 and revise it to reflect, “AND PRINCIPAL DIAGNOSIS OF HIV RELATED CONDITION”.

#### 10. Review of Procedure Codes in MS-DRGs 981 Through 983 and 987 Through 989

We annually conduct a review of procedures producing assignment to MS-DRGs 981 through 983 (Extensive

O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS-DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS-DRGs into one of the surgical MS-DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS-DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

Based on the results of our review of the claims data from the September 2025 update of the FY 2025 MedPAR file of cases found to group to MS-DRGs 981 through 983 or MS-DRGs 987 through 989, we did not identify any cases for reassignment and are not proposing to move any cases from MS-DRGs 981 through 983 or MS-DRGs 987 through 989 into a surgical MS-DRG for the MDC into which the principal diagnosis or procedure is assigned.

In addition to the internal review of procedures producing assignment to MS-DRGs 981 through 983 or MS-DRGs 987 through 989, we also consider requests that we receive to examine cases found to group to MS-DRGs 981 through 983 or MS-DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS-DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS-DRGs to which the procedure codes are assigned. We did not receive any requests suggesting reassignment.

We also review the list of ICD-10-PCS procedure codes that, when in combination with their principal diagnosis code, result in assignment to MS-DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedure codes should be reassigned from one of those two groups of MS-DRGs to the other group of MS-



DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS-DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS-DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedure codes for which we have an adequate number of discharges to analyze the data.

Additionally, we also consider requests that we receive to examine cases found to group to MS-DRGs 981 through 983 or MS-DRGs 987 through 989 to determine if it would be appropriate for the cases to be reassigned from one of the MS-DRG groups to the other. Based on the results of our review of the claims data from the September 2025 update of the FY 2025 MedPAR file we did not identify any cases for reassignment. We also did not receive any requests suggesting reassignment. Therefore, for FY 2027 we are not proposing to move any cases reporting procedure codes from MS-DRGs 981 through 983 to MS-DRGs 987 through 989 or vice versa.

## 11. Operating Room (O.R.) and Non-O.R. Procedures

### a. Background

Under the IPPS MS-DRGs (and former CMS MS-DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed.

Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.). Currently, each ICD-10-PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS-DRG assignment. First, each ICD-10-PCS procedure code is either

designated as an O.R. procedure for purposes of MS-DRG assignment (“O.R. procedures”) or is not designated as an O.R. procedure for purposes of MS-DRG assignment (“non-O.R. procedures”). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS-DRG assignment or not affecting the MS-DRG assignment. We refer to these designations that do affect MS-DRG assignment as “non-O.R. affecting the MS-DRG.” For new procedure codes that have been finalized through the ICD-10 Coordination and Maintenance Committee code update process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS-DRG, we recommend the MS-DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS-DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS-DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.C.15 of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, we are making Table 6B.—New Procedure Codes—FY 2027 available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.html>. We also refer readers to the ICD-10 MS-DRG Version 43.1 Definitions Manual at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.html> for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS-DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS-DRG Index.

In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19230), we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to

conduct a comprehensive, systematic review of the ICD-10-PCS procedure codes. This will be a multiyear project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD-10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD-10-PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD-10.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19230) that, as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. designation. We intend to consider the resources used and how a procedure should affect the MS-DRG assignment. We may also consider the effect of certain surgical approaches to evaluate whether to subdivide a subset of MS-DRGs based on a specific surgical approach. We stated we plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS-DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD-10 MS-DRGs to better recognize complexity of service and resource utilization.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58540 through 58541), we provided a summary of the comments we had received in response to our request for feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD-10-PCS classification system for future consideration. We also stated that in consideration of the PHE, we believed it



may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review.

For this FY 2027 IPPS/LTCH PPS proposed rule, we continue to believe additional time is necessary as we continue to develop our process and methodology. As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58749), we have signaled in prior rulemaking that the designation of an O.R. procedure encompasses more than the physical location of the hospital room in which the procedure may be performed; in other words, the performance of a procedure in an operating room is not the sole determining factor we will consider as we examine the designation of a procedure in the ICD-10-PCS classification system. We are exploring alternatives on how we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is available in the ICD-10 claims data. We are considering the feedback received on what factors and/or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD-10-PCS classification system as we continue to develop our process and methodology and will provide more detail on this analysis and the methodology for conducting this comprehensive review in future rulemaking. We encourage the public to continue to submit feedback and comments on any other factors in consideration of our refinement efforts to recognize and differentiate consumption of resources under the ICD-10 MS-DRGs.

For this FY 2027 IPPS/LTCH PPS proposed rule, we received requests regarding changing the designation of specific ICD-10-PCS procedure codes from non-O.R. to O.R. procedures. In this section of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, we detail and respond to those requests. In this section of the preamble of this proposed rule, we also discuss any proposals we are making based on our internal review and analysis and the process that was utilized for evaluating each procedure code. For each procedure, we consider—

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a non-extensive procedure; and
- To which MS-DRGs the procedure should be assigned.

We note that many MS-DRGs require the presence of any O.R. procedure. As a result, cases with a principal diagnosis

associated with a particular MS-DRG would, by default, be grouped to that MS-DRG. Therefore, we do not list these MS-DRGs in our discussion in this section of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule. Instead, we only discuss MS-DRGs that require explicitly adding the relevant procedure codes to the Grouper logic in order for those procedure codes to affect the MS-DRG assignment as intended.

For procedures that would not typically require the resources of an operating room, we determined if the procedure should affect the MS-DRG assignment. In cases where we are proposing to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, we also are proposing one or more MS-DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned.

In addition, cases that contain O.R. procedures will map to MS-DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS-DRGs 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS-DRGs 981 through 989 in order for this to occur. Therefore, we do not specifically address that aspect in summarizing the request and our response to that request or the proposals we make based on our internal review and analysis in this section of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule.

#### b. Non-O.R. Procedures to O.R. Procedures

##### (1) Introduction of Allogeneic Pancreatic Islet Cellular Suspension

For this FY 2027 IPPS/LTCH PPS proposed rule, we received a request to change the designation of ICD-10-PCS code XW033DA (Introduction of donislecel-jujn allogeneic pancreatic islet cellular suspension into peripheral vein, percutaneous approach, new technology group 10) from a non-O.R. procedure to a O.R. procedure.

Donislecel-jujn (Lantidra™) is Food & Drug Administration (FDA) approved as an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with type 1 diabetes (T1D) who are unable to approach target HbA1c because of current, repeated episodes of severe hypoglycemia despite intensive

diabetes management and education. Donislecel-jujn (Lantidra™) consists of a suspension of allogeneic pancreatic islets of Langerhans derived from a donor pancreas in buffered transplant medium containing sodium chloride, dextrose, minerals, amino acids, vitamins, and other compounds supplemented with HEPES (2-[4-(2-hydroxyethyl) piperazin-1-yl] ethanesulfonic acid; 10 mM final concentration) and human serum albumin (0.5% final concentration).

In the ICD-10 MS-DRGs Definitions Manual Version 43.1, procedure code XW033DA is currently designated as a non-O.R. procedure affecting assignment to MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively). We refer the reader to the ICD-10 MS-DRG Version 43.1 Definitions Manual (which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software> for complete documentation of the Grouper logic for the MS-DRGs 673, 674, and 675.

According to the requestor, the clinical characteristics and costs of cases assigned to MS-DRGs 673 through 675 are significantly different from those associated with the administration of donislecel-jujn (Lantidra™). The requestor states that the cost of donislecel-jujn (Lantidra™) is high due to complex and highly regulated manufacturing processes for biologic cell products. According to the requestor, code XW033DA should be assigned to Pre MDC MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies) because donislecel-jujn (Lantidra™) is similar to other CAR-T technologies that map to DRG 018 as a cellular product, and in regard to procedure complexity, high cost, and is indicated for a rare patient population.

We reviewed this issue and note a proposal to create a procedure code that describes the administration of donislecel-jujn was presented and discussed at the March 19–20, 2024 ICD-10 Coordination and Maintenance Committee meeting and subsequently finalized. For new procedure codes that have been finalized through the ICD-10 Coordination and Maintenance Committee code update process, we recommend the O.R. designation, which is generally based on the assignment of predecessor codes or the assignment of similar codes. Consistent with our annual process of assigning new procedure codes to MDCs and MS-

DRGs and designating a procedure as an O.R. or non-O.R. procedure, we reviewed the predecessor procedure code assignment. The predecessor code for procedure code XW033DA is procedure code 3E033U1 (Introduction of nonautologous pancreatic islet cells into peripheral vein, percutaneous approach) which is designated as a non-O.R. procedure affecting assignment to MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively).

We analyzed claims data from the September 2025 update of the FY 2025 MedPAR file for MS-DRGs 673, 674, and 675 for cases reporting procedure code XW033DA and did not find any cases. We then extended our analysis to all MS-DRGs and again did not find any cases. We note that these procedures do not typically require the resources of an operating room and are not surgical in nature. As such, we disagree with designating procedure code XW033DA, which describes the intravenous portal vein administration of donislecel-jujn, as an O.R. procedure.

In reviewing this request, we note the underlying intent of this request is to change the MS-DRG assignment of procedure code XW033DA from MS-DRGs 673, 674, and 675 to MS-DRG 018. In regard to the reassignment of procedure code XW033DA to MS-DRG 018, we note that the category of cell and gene therapies continues to evolve. As discussed in prior rulemaking (90 FR 36554 through 36560), we are in the process of carefully considering the feedback we have previously received about ways in which we can continue to appropriately reflect resource utilization associated with cell and gene therapies while maintaining clinical coherence and stability in the relative weights under the IPPS MS-DRGs. We continue to examine these complex issues in consideration for future rulemaking. We acknowledge that there may be distinctions to account for as we continue to gain more experience in the use of these therapies and have additional claims data to analyze. We believe this topic, relating to the administration of donislecel-jujn (Lantidra™), an allogeneic (donor)

pancreatic islet cellular therapy, is appropriately aligned with and should be considered as part of that broader effort.

Therefore, for the reason discussed, we are proposing to maintain the current designation of procedure code XW033DA as “non-O.R. affecting the MS-DRG” for FY 2027. We refer the reader to the discussion in section II.C.6.b. of this FY 2027 IPPS/LTCH PPS proposed rule, regarding the proposed modifications for cases currently mapping to MS-DRGs 673, 674, and 675, effective October 1, 2026, for FY 2027.

#### (2) Percutaneous Introduction of AGN1 Bone Void Filler Into Bones

One requestor identified ICD 10-PCS procedure code XW0V3WA (Introduction of AGN1 bone void filler into bones, percutaneous approach, new technology group 10) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS-DRG assignment. The requestor noted that the Local Osteo-Enhancement Procedure (LOEP) is an investigational surgical procedure designed to mechanically strengthen the proximal femur to reduce the risk of hip fractures in patients who are known to have weakened bones or other factors leading to a high risk of hip fracture. According to the requestor, the AGN1 LOEP Kit is expected to be indicated to reduce the risk of hip fracture in patients at risk of fragility fracture and require access to specialized equipment only available in the operating room (including anesthesia, C-arm, operating table, etc.). The requestor stated that FDA approval of the AGN1 LOEP Kit is anticipated in late 2027. According to the requestor, there may be situations where the procedure could be performed as a standalone procedure. The requestor noted the procedure may be performed under any one of the following three clinical scenarios (1) unilateral, standalone cases: a patient has one hip treated in a scheduled procedure, (2) bilateral, standalone cases: a patient has both hips treated in a scheduled procedure, or (3) concomitant to an index hip fragility fracture in the unfractured, contralateral hip: a patient

has their index hip fracture repaired and then the procedure utilizing the LOEP kit is performed to treat the unfractured, contralateral hip during the same operative session. Therefore, the requestor stated that this procedure should be recognized as an O.R. procedure for purposes of MS-DRG assignment.

We agree with the requestor that in the ICD-10 MS-DRGs Definitions Manual Version 43.1, procedure code XW0V3WA is designated as a non-O.R. procedure for purposes of MS-DRG assignment; therefore, when the introduction of AGN1 bone void filler is reported with a procedure code that describes a surgical procedure, the ICD-10-PCS code describing the surgical procedure will determine the surgical MS-DRG assignment based on the principal diagnosis reported.

We reviewed this issue and note a proposal to create a procedure code that describes the percutaneous introduction of AGN1 bone void filler into bones was presented and discussed at the September 12–13, 2023 ICD-10 Coordination and Maintenance Committee meeting and subsequently finalized. For new procedure codes that have been finalized through the ICD-10 Coordination and Maintenance Committee code update process, we recommend the O.R. designation, which is generally based on the assignment of predecessor codes or the assignment of similar codes. Consistent with our annual process of assigning new procedure codes to MDCs and MS-DRGs and designating a procedure as an O.R. or non-O.R. procedure, we reviewed the predecessor procedure code assignment. The predecessor code for procedure code XW0V3WA is procedure code 3E0V3GC (Introduction of other therapeutic substance into bones, percutaneous approach) which is designated as a non-O.R. procedure.

To evaluate the frequency with which procedure code XW0V3WA is reported for different clinical scenarios, we examined claims data from the September 2025 update of the FY 2025 MedPAR file to determine the MS-DRGs reporting procedure code XW0V3WA. Our findings are shown in the following table.

| CASES REPORTING ICD-10-PCS CODE XW0V3WA |                                                                                  |                 |                        |                 |
|-----------------------------------------|----------------------------------------------------------------------------------|-----------------|------------------------|-----------------|
| MS-DRG                                  | Description                                                                      | Number of Cases | Average Length of Stay | Average Costs   |
| 466                                     | Revision of Hip or Knee Replacement with MCC                                     | 1               | 20                     | \$29,229        |
| 482                                     | Hip and Femur Procedures Except Major Joint without CC/MCC                       | 1               | 3                      | \$19,276        |
| 486                                     | Knee Procedures with Principal Diagnosis of Infection with CC                    | 1               | 7                      | \$24,361        |
| 494                                     | Lower Extremity and Humerus Procedures Except Hip, Foot and Femur without CC/MCC | 1               | 1                      | \$6,941         |
| <b>Total</b>                            |                                                                                  | <b>4</b>        | <b>7.8</b>             | <b>\$19,952</b> |

There were four cases reporting the percutaneous introduction of AGN1 bone void filler into bones with procedure code XW0V3WA. Overall, the data indicate that the percutaneous introduction of AGN1 bone void filler into bones was not the underlying reason for, or main driver of, resource utilization for those cases. As shown in the table, when the procedure code XW0V3WA is reported, the MS-DRGs assigned are classified as surgical MS-DRGs which indicates that at least one procedure code designated as an O.R. procedure was also reported in these cases. We refer the reader to the ICD-10 MS-DRG Version 43.1 Definitions Manual (which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>) for complete documentation of the GROUPER logic for the listed MS-DRGs.

After reviewing the claims data, we believe it is premature to consider a proposal to change the designation of the procedure code that describes the percutaneous introduction of AGN1 bone void filler into bones. While the September 2025 update of the FY 2025 MedPAR file does contain claims reporting the percutaneous introduction of AGN1 bone void filler into bones, the number of cases is small across the MS-DRGs. Additionally, as stated previously, when the procedure code XW0V3WA is reported, the MS-DRGs assigned are classified as surgical MS-DRGs, which indicates that at least one procedure code designated as an O.R. procedure was also reported in these cases. We do not have claims data to further examine the impact of the percutaneous introduction of AGN1 bone void filler into bones when performed as a standalone procedure. The claims data also reflect a wide variance with regard to the average costs and average lengths of stay for the cases reporting the percutaneous introduction of AGN1 bone void filler into bones. As such, we disagree with designating the procedure code that describes the percutaneous introduction of AGN1 bone void filler into bones as an O.R. procedure for FY 2027.

As noted previously, the Local Osteo-Enhancement Procedure (LOEP) is an investigational surgical procedure. In the absence of additional data, we believe that more time is needed to consider the clinical characteristics and resource utilization associated with this procedure before considering changing the designation of the procedure code to an O.R. procedure. In future years, we expect we will have additional data that could be used to evaluate the O.R.

designation of procedure code XW0V3WA.

Therefore, for the reasons discussed, we are proposing to maintain the designation of procedure code XW0V3WA as non-O.R. for FY 2027.

## 12. Proposed Changes to the MS-DRG Diagnosis Codes for FY 2027

### a. Background of the CC List and the CC Exclusions List

Under the IPPS MS-DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (NonCC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

### b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as an MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when assigning severity levels to new codes and when receiving

requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) that with the transition to ICD-10-CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD-10-CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the proposed severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 IPPS/LTCH PPS final rule, we generally did not finalize our proposed changes to the severity designations for the ICD-10-CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16 (Resistance to antimicrobial drugs) from a NonCC to a CC. We stated that postponing adoption of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the proposed severity level designation changes for FY 2020.

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to <https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/Downloads/10082019ListingSessionTranscriptandQandAandAudioFile.zip> for the transcript and audio file of the listening session. We also refer readers to <https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/AcuteInpatientPPS/MS-DRG->

*Classifications-and-Software.html* for the supplementary file containing the mathematical data generated using claims from the FY 2018 MedPAR file describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554), we discussed our plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles and plan to present the findings and proposals in future rulemaking. The nine guiding principles are as follows:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation or management of care or both.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for a complete summation of the comments we received for each of the nine guiding principles and our responses to those comments.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175 through 25180), as another interval step in our comprehensive review of the severity designations of ICD–10–CM diagnosis codes, we requested public comments on a potential change to the severity level designations for “unspecified” ICD–10–CM diagnosis codes that we were considering adopting for FY 2022. Specifically, we noted we were considering changing the severity level designation of “unspecified” diagnosis codes to a NonCC where there are other

codes available in that code subcategory that further specify the anatomic site. As summarized in the FY 2022 IPPS/LTCH PPS final rule, many commenters expressed concern with the potential severity level designation changes overall and recommended that CMS delay any possible change to the designation of these codes to give hospitals and their physicians time to prepare. After careful consideration of the public comments we received, we maintained the severity level designation of the “unspecified” diagnosis codes currently designated as a CC or MCC where there are other codes available in that code subcategory that further specify the anatomic site for FY 2022. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44916 through 44926) for a complete discussion of our response to public comments regarding the potential severity level designation changes. Instead, for FY 2022, we finalized a new MCE code edit for “unspecified” codes, effective with discharges on and after April 1, 2022. We stated we believe finalizing this new edit would provide additional time for providers to be educated while not affecting the payment the provider is eligible to receive. We refer the reader to section II.D.14.e. of the preamble of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943) for the complete discussion.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48866), we stated that as the new unspecified edit became effective beginning with discharges on and after April 1, 2022, we believed it was appropriate to not propose to change the designation of any ICD–10–CM diagnosis codes, including the unspecified codes that are subject to the “Unspecified Code” edit, as we continue our comprehensive CC/MCC analysis to allow interested parties the time needed to become acclimated to the new edit.

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28177 through 28181), we also requested public comments on how the reporting of diagnosis codes in categories Z55–Z65 might improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS–DRGs. We stated we were also interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58755 through 58759), based on our analysis of the impact on resource use for the ICD–10–CM Z codes that describe homelessness and after consideration of public comments, we finalized changes to the severity levels for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness), from NonCC to CC. In the FY 2025 proposed rule (89 FR 35995), we noted that since the FY 2021 IPPS/LTCH PPS final rule we have continued to solicit feedback regarding the nine guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. We stated we had encouraged the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code when providing feedback or comments. We also noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26748 through 26750) we illustrated how the nine guiding principles might be applied in evaluating changes to the severity designations of diagnosis codes in our discussion of our proposed changes to the severity level designation for certain diagnosis codes that describe homelessness. After consideration of the ongoing feedback and comments we had received, we proposed to finalize the nine guiding principles. After consideration of the public comments received, and for the reasons discussed, we finalized the nine guiding principles as listed previously in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69076 through 69078). Accordingly, we stated that our evaluations to determine the extent to which the presence of a diagnosis code as a secondary diagnosis results in increased hospital resource use will include a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of the nine guiding principles.

Additionally, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69079 through 69084), based on our analysis of the impact on resource use for the ICD–10–CM diagnosis codes that describe inadequate housing and housing instability, and after consideration of public comments, we finalized changes to the severity levels for seven diagnosis codes for FY 2025. We refer the reader to the following section of this proposed rule for our proposed changes to the severity level designation for the

diagnosis codes that describe homelessness, inadequate housing and housing instability for FY 2027.

We have updated the Impact on Resource Use Files on the CMS website so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 through the FY 2025 MedPAR files. These files are posted on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software>.

For new diagnosis codes approved for FY 2027, consistent with our annual process for designating a severity level (MCC, CC, or NonCC) for new diagnosis codes, we first review the predecessor code designation, followed by review and consideration of other factors that may be relevant to the severity level designation, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We note that this process does not automatically result in the new

diagnosis code having the same designation as the predecessor code. We refer the reader to section II.C.13 of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule for the discussion of the proposed changes to the ICD-10-CM and ICD-10-PCS coding systems for FY 2027.

#### c. Proposed Changes to Severity Levels

##### 1. SDOH—Homelessness, Inadequate Housing, and Housing Instability

As discussed earlier in this section, in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58755 through 58759), we finalized changes to the severity levels for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness), from NonCC to CC. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69079 through 69084), we finalized changes to the severity levels for seven diagnosis codes that describe inadequate housing and housing instability from NonCC to CC. We stated CMS would further examine the claims data and consider

future changes to the designation of the SDOH Z codes when reported as a secondary diagnosis. We further stated CMS would continue to monitor and evaluate the reporting of the diagnosis codes describing social and economic circumstances.

In continuation of our examination of the SDOH Z codes, for this FY 2027 IPPS/LTCH PPS proposed rule, we reviewed the mathematical data on the impact on resource use for the ICD-10-CM Z codes that describe homelessness, inadequate housing, and housing instability. The following table reflects the impact on resource use data generated using claims from the September 2025 update of the FY 2025 MedPAR file. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our historical approach to mathematically evaluate the extent to which the presence of an ICD-10-CM code as a secondary diagnosis resulted in increased hospital resource use, and a more detailed explanation of the columns in the table.

| ICD-10-CM Code <sup>a</sup> | Description <sup>b</sup>                                    | Total Count <sup>c</sup> | Cnt1 <sup>d</sup> | C1 <sup>e</sup> | Cnt2 <sup>f</sup> | C2 <sup>g</sup> | Cnt3 <sup>h</sup> | C3 <sup>i</sup> |
|-----------------------------|-------------------------------------------------------------|--------------------------|-------------------|-----------------|-------------------|-----------------|-------------------|-----------------|
| Z59.00                      | Homelessness unspecified                                    | 30,603                   | 3,308             | 1.67            | 13,544            | 2.24            | 13,751            | 3.24            |
| Z59.01                      | Sheltered homelessness                                      | 14,271                   | 1,538             | 1.81            | 6,236             | 2.28            | 6,497             | 3.23            |
| Z59.02                      | Unsheltered homelessness                                    | 8,023                    | 712               | 2.03            | 3,528             | 2.35            | 3,783             | 3.32            |
| Z59.10                      | Inadequate housing, unspecified                             | 2,019                    | 74                | 1.97            | 853               | 2.16            | 1,092             | 3.03            |
| Z59.11                      | Inadequate housing environmental temperature                | 753                      | 32                | 1.96            | 281               | 1.76            | 440               | 3.10            |
| Z59.12                      | Inadequate housing utilities                                | 3,541                    | 196               | 1.61            | 1,497             | 2.20            | 1,848             | 3.07            |
| Z59.19                      | Other inadequate housing                                    | 2,277                    | 145               | 1.62            | 904               | 2.63            | 1,228             | 3.27            |
| Z59.811                     | Housing instability, housed, with risk of homelessness      | 14,069                   | 720               | 1.02            | 5,215             | 2.13            | 8,134             | 3.07            |
| Z59.812                     | Housing instability, housed, homelessness in past 12 months | 593                      | 37                | 1.83            | 268               | 2.42            | 288               | 3.04            |
| Z59.819                     | Housing instability, housed unspecified                     | 10,565                   | 643               | 1.35            | 4,295             | 2.08            | 5,627             | 3.09            |

<sup>a</sup> This column is the secondary diagnosis code (SDX).

<sup>b</sup> This column is the title of the SDX.

<sup>c</sup> The total count of discharge claims with the SDX.

<sup>d</sup> Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.

<sup>e</sup> "C1" impact on resource use of the SDX for discharge claims in "Cnt1".

<sup>f</sup> Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.

<sup>g</sup> "C2" impact on resource use of the SDX for discharge claims in "Cnt2".

<sup>h</sup> Count of discharge claims with the SDX and with at least one other SDX that is a MCC.

<sup>i</sup> "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

We reviewed the findings from these data. As reflected in the table, the C1 findings ranged from a low of 1.02 to a high of 2.03. A value close to 2.0 in the C1 field suggests that the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. Because the C1 values in the table

are generally close to 2, the mathematical data suggest that when these SDOH Z codes are reported as a secondary diagnosis increased resources are involved in caring for patients experiencing these circumstances, however we note that these SDOH Z

codes describe social circumstances and not medical conditions or illnesses.

As previously noted, in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization

of diagnoses as an MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We noted in the FY 2008 IPPS/LTCH PPS final rule that as a result of the changes that had occurred during the years since the implementation of the IPPS, the CC list as defined at the time had lost much of its capacity to discriminate hospital resource use. The need for a revised CC list prompted a reexamination of the secondary diagnoses that qualify as a CC. Therefore, our efforts to better recognize severity of illness began with a comprehensive review of the CC list. Our intent was to better distinguish cases that are likely to result in increased hospital resource use based on secondary diagnoses.

We stated in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47153) that certain diagnoses, such as chronic illness diagnoses, do not cause a significant increase in hospital resource use unless there is an acute exacerbation present or there is a significant deterioration in the underlying chronic condition. Therefore, in the revised CC list, we removed chronic diseases without a significant acute manifestation. We stated that recognition of the impact of the chronic disease is accomplished by separately coding the acute manifestation.

In our further examination of the claims data and the current designation of the ICD-10-CM Z codes that describe homelessness, inadequate housing, and housing instability when reported as a

secondary diagnosis, we now believe that similar to our analysis of the chronic illness diagnoses, change of designation from NonCC to CC should be based on the expected resource use associated with the treatment of an underlying medical condition or illness rather than social circumstances. Specifically, we believe that recognition of the contribution that patient social and economic circumstances, such as homelessness, inadequate housing, and housing instability, add to the complexity of acute hospital care should be accomplished by separately coding those diagnoses that describe an acute exacerbation or deterioration of an underlying medical condition or illness, similar to the approach we undertook in categorizing chronic illness diagnoses as stated in the FY 2008 IPPS/LTCH PPS final rule. While we continue to include a mathematical analysis of claims data in evaluating the extent to which the presence of a diagnosis code as a secondary diagnosis results in increased hospital resource use, as previously described, we believe that in the context of the ICD-10-CM Z codes that describe social circumstances, it is more appropriate to align our analysis with our intent as stated in the FY 2008 IPPS/LTCH PPS final rule with respect to chronic illness diagnoses (that is, recognition of the contribution to the complexity of hospital care would be accomplished by separately coding those diseases on the CC list that are associated with an acute exacerbation or deterioration of the underlying medical condition or illness (72 FR 47154)). Accordingly, we believe that categorization of a diagnosis code as an

MCC, a CC, or a NonCC should recognize the clinical complexity and expected resource consumption for the treatment of an underlying medical condition or illness, and not social circumstances. Therefore, we are proposing to change the severity level designation of diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), Z59.02 (Unsheltered homelessness), Z59.10 (Inadequate housing, unspecified), Z59.11 (Inadequate housing environmental temperature), Z59.12 (Inadequate housing utilities), Z59.19 (Other inadequate housing), Z59.811 (Housing instability, housed, with risk of homelessness), Z59.812 (Housing instability, housed, homelessness in past 12 months) and Z59.819 (Housing instability, housed unspecified) from CC to NonCC for FY 2027.

## 2. Newborn Affected by Malpresentation Before Labor

For this FY 2027 IPPS/LTCH PPS proposed rule, we received a request to change the severity level designations of the ICD-10-CM diagnosis codes P01.7 (Newborn affected by malpresentation before labor) and P03.0 (Newborn affected by breech delivery and extraction) from NonCC to CC. The requestor did not provide additional rationale for this request.

To evaluate this request, we analyzed the claims data in the September 2025 update of the FY 2025 MedPAR file. The following table shows the analysis for each of the diagnosis codes identified by the requestor.

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| ICD-10-CM Code <sup>a</sup> | Description <sup>b</sup>                           | Total Count <sup>c</sup> | Cnt1 <sup>d</sup> | C1 <sup>e</sup> | Cnt2 <sup>f</sup> | C2 <sup>g</sup> | Cnt3 <sup>h</sup> | C3 <sup>i</sup> |
|-----------------------------|----------------------------------------------------|--------------------------|-------------------|-----------------|-------------------|-----------------|-------------------|-----------------|
| P01.7                       | Newborn affected by malpresentation before labor   | -                        | -                 | -               | -                 | -               | -                 | -               |
| P03.0                       | Newborn affected by breech delivery and extraction | -                        | -                 | -               | -                 | -               | -                 | -               |

<sup>a</sup> This column is the secondary diagnosis code (SDX).

<sup>b</sup> This column is the title of the SDX.

<sup>c</sup> The total count of discharge claims with the SDX.

<sup>d</sup> Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.

<sup>e</sup> "C1" impact on resource use of the SDX for discharge claims in "Cnt1".

<sup>f</sup> Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.

<sup>g</sup> "C2" impact on resource use of the SDX for discharge claims in "Cnt2".

<sup>h</sup> Count of discharge claims with the SDX and with at least one other SDX that is a MCC.

<sup>i</sup> "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

As reflected in the table, we found zero instances where diagnosis codes P01.7 or P03.0 were reported as secondary diagnoses. In considering the nine guiding principles, as summarized previously, we note that fetal malpresentation is any position of the

fetus at birth where the head is not the presenting part. Common types include breech (bottom/feet first), transverse (sideways), or oblique lie. While normal in early pregnancy, most babies turn; however, if still malpresenting at term, management often involves external

cephalic version (ECV) to turn the baby or a planned C-section due to risks like cord prolapse during vaginal delivery. A higher level of care for the mother (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length

of stay) may be warranted depending on the treatment or management of the fetal malpresentation pursued by the attending provider.

Based on the lack of claims data to evaluate to consider a severity level change, we believe that the ICD-10-CM diagnosis codes P01.7 and P03.0 should remain designated as NonCCs. Therefore, we are proposing to maintain the severity level designation of codes P01.7 and P03.0 as NonCCs for FY 2027. We will continue to monitor the claims data in consideration of any future modifications to the severity level designation of diagnosis codes P01.7 and P03.0.

### 3. Functional Quadriplegia

For this FY 2027 IPPS/LTCH PPS proposed rule, we received a request to

change the severity level designation of ICD-10-CM diagnosis code R53.2 (Functional quadriplegia) from MCC to NonCC. According to the requestor, code R53.2 describes patients who are unable to move any of their extremities, not because of a spinal cord or focal brain dysfunction, but because of global dysfunction such as severe dementia or contractures. The requestor further stated that the definition of functional quadriplegia does not exist in medical literature; therefore, the vagueness of the condition described by code R53.2 leads to the code being overused. The requestor also questioned whether an immobile patient during an inpatient stay utilizes more resources than other patients with very limited mobility.

We agree that that diagnosis code R53.2 (Functional quadriplegia) is

currently designated as an MCC. We refer the reader to Appendix H of the ICD-10 MS-DRG Version 43.1 Definitions Manual (available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drug-classifications-and-software>) for the complete list of diagnoses designated as MCCs when reported as secondary diagnoses, except when used in conjunction with the principal diagnosis in the corresponding CC Exclusion List in Appendix C.

To evaluate this request, we analyzed the claims data in the September 2025 update of the FY 2025 MedPAR file. The following table shows the analysis for diagnosis code R53.2.

| ICD-10-CM Code <sup>a</sup> | Description <sup>b</sup> | Total Count <sup>c</sup> | Cnt1 <sup>d</sup> | C1 <sup>e</sup> | Cnt2 <sup>f</sup> | C2 <sup>g</sup> | Cnt3 <sup>h</sup> | C3 <sup>i</sup> |
|-----------------------------|--------------------------|--------------------------|-------------------|-----------------|-------------------|-----------------|-------------------|-----------------|
| R53.2                       | Functional quadriplegia  | 40,455                   | 782               | 2.05            | 8,287             | 2.58            | 31,386            | 3.38            |

<sup>a</sup> This column is the secondary diagnosis code (SDX).

<sup>b</sup> This column is the title of the SDX.

<sup>c</sup> The total count of discharge claims with the SDX.

<sup>d</sup> Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.

<sup>e</sup> "C1" impact on resource use of the SDX for discharge claims in "Cnt1".

<sup>f</sup> Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.

<sup>g</sup> "C2" impact on resource use of the SDX for discharge claims in "Cnt2".

<sup>h</sup> Count of discharge claims with the SDX and with at least one other SDX that is a MCC.

<sup>i</sup> "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

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We analyzed these data as described in FY 2008 IPPS final rule (72 FR 47158 through 47161). The table shows that the C1 values of the diagnosis code that describes causally functional quadriplegia is 2.05. A C1 value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C2 finding of diagnosis code R53.2 is 2.58. C2 values close to 3.0 suggests the condition is more similar to an MCC than a CC or non-CC. The C2 findings support maintaining the code R53.2 as an MCC. The data are clearly mixed between the C1 and C2 findings and does not consistently support a change in the severity level.

In considering the nine guiding principles, as summarized previously, we note that functional quadriplegia is the inability to move due to another condition (*e.g.*, dementia, severe contractures, arthritis, etc.). It is a diagnosis that can impede patient cooperation or management of care or both. Patients diagnosed with functional quadriplegia can require a higher level of care by needing intensive monitoring, and a greater number of caregivers as

the patient does not have the ability to ambulate.

After considering the C1, and C2 values of ICD-10-CM diagnosis code R53.2, the lack of consistent claims data to support a severity level change, and consideration of the nine guiding principles, we believe R53.2 should remain designated as an MCC. Therefore, we are proposing to maintain the severity level designation of ICD-10-CM diagnosis code R53.2 as an MCC for FY 2027.

### 4. Malnutrition

For this FY 2027 IPPS/LTCH PPS proposed rule, we received a request to change the severity level designation of the following diagnosis codes from MCC to NonCC:

- E40 (Kwashiorkor)
- E41 (Nutritional marasmus)
- E42 (Marasmic kwashiorkor)
- E43 (Unspecified severe protein-calorie malnutrition)

According to the requestor, the criteria for the ICD-10-CM diagnosis codes that describe malnutrition are vague. The requestor stated that nutritional assessment is the standard of care for all hospital admissions, and the short-term weight loss that often occurs

in the hospital as a result of keeping patients with an empty stomach (*i.e.*, nothing by mouth) for other interventions does not signal real malnutrition requiring intensive treatment. In circumstances when treatment is initiated, for example increasing the intake of calories or protein, the treatment adds little or no additional costs to overall resource utilization for the encounter.

We agree that diagnosis codes E40, E41, E42, and E43 are currently designated as MCCs. We refer the reader to Appendix H of the ICD-10 MS-DRG Version 43.1 Definitions Manual (available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drug-classifications-and-software>) for the complete list of diagnoses designated as MCCs when reported as secondary diagnoses, except when used in conjunction with the principal diagnosis in the corresponding CC Exclusion List in Appendix C.

To evaluate this request, we analyzed the claims data in the September 2025 update of the FY 2025 MedPAR file. The following table shows the analysis for

each of the diagnosis codes identified by the requestor.

| ICD-10-CM Code <sup>a</sup> | Description <sup>b</sup>                        | Total Count <sup>c</sup> | Cnt1 <sup>d</sup> | C1 <sup>e</sup> | Cnt2 <sup>f</sup> | C2 <sup>g</sup> | Cnt3 <sup>h</sup> | C3 <sup>i</sup> |
|-----------------------------|-------------------------------------------------|--------------------------|-------------------|-----------------|-------------------|-----------------|-------------------|-----------------|
| E40                         | Kwashiorkor                                     | 35                       | -                 | -               | 10                | 2.84            | 25                | 3.43            |
| E41                         | Nutritional marasmus                            | 74                       | -                 | -               | 15                | 2.38            | 59                | 3.59            |
| E42                         | Marasmic kwashiorkor                            | 15                       | 1                 | 0.73            | 6                 | 3.21            | 8                 | 3.16            |
| E43                         | Unspecified severe protein-calorie malnutrition | 383,399                  | 5,821             | 2.07            | 131,245           | 2.52            | 246,333           | 3.38            |

<sup>a</sup> This column is the secondary diagnosis code (SDX).

<sup>b</sup> This column is the title of the SDX.

<sup>c</sup> The total count of discharge claims with the SDX.

<sup>d</sup> Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.

<sup>e</sup> "C1" impact on resource use of the SDX for discharge claims in "Cnt1".

<sup>f</sup> Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.

<sup>g</sup> "C2" impact on resource use of the SDX for discharge claims in "Cnt2".

<sup>h</sup> Count of discharge claims with the SDX and with at least one other SDX that is a MCC.

<sup>i</sup> "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

We analyzed these data as described in FY 2008 IPPS final rule (72 FR 47158 through 47161). The table above shows that the C1 findings ranged from a low of 0.73 to a high of 2.07. As stated earlier, a C1 value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C1 findings suggest that these codes are more like a CC than an MCC. However, the C2 findings ranged from a low of 2.38 to a high of 3.21. Values close to 3.0 suggests the conditions are more similar to an MCC than a CC or non-CC. The C2 findings support maintaining the malnutrition codes identified by the requestor as MCCs. The data are clearly mixed between the C1 and C2 findings and does not consistently support a change in the severity level.

In considering the nine guiding principles, as summarized previously, we note that the World Health Organization (WHO) defines malnutrition as "deficiencies, excesses or imbalances in a person's intake of energy and/or nutrients." Protein-calorie malnutrition is observed most frequently in developing countries but has been described with increasing frequency in hospitalized and chronically ill children in the United States. The distinction between the two forms of protein-calorie malnutrition is based on the presence of edema (kwashiorkor) or absence of edema (marasmus). Marasmus involves inadequate intake of protein and calories, whereas kwashiorkor involves fair-to-normal calorie intake with inadequate protein intake. In developed countries such as the United States,

inadequate food intake is a less common cause of malnutrition. Instead, diseases and, in particular, chronic illnesses play an important role in the etiology of malnutrition. As such, the conditions described by the ICD-10-CM diagnosis codes identified by the requestor reflect systemic impact and serve as a marker for advanced disease states across multiple different comorbid conditions.

After considering the C1, and C2 values of ICD-10-CM diagnosis codes E40, E41, E42, and E43, the lack of consistent claims data to support a severity level change, and consideration of the nine guiding principles, we believe E40, E41, E42, and E43 should remain designated as MCCs. Therefore, we are proposing to maintain the severity level designation of ICD-10-CM diagnosis codes E40, E41, E42, and E43 as MCCs for FY 2027.

#### 5. Prolonged First Stage (of Labor)

For this FY 2027 IPPS/LTCH PPS proposed rule, we received a request to change the severity level designation of ICD-10-CM diagnosis code O63.0 (Prolonged first stage (of labor)) from NonCC to CC. According to the requestor, prolonged labor increases length of stay by up to two days and significantly increases resources required to care for these patients. The requestor performed their own analysis of the Impact on Resource Use File on the CMS website generated using claims from the FY 2024 MedPAR file and found that when reported as a secondary diagnosis, O63.0 had a C1 value higher than 2, and C2 and C3 values of at least close to 2, which suggests the code should be designated

as a CC. Additionally, in their own analysis of the Impact on Resource Use File on the CMS website generated using claims from the FY 2024 MedPAR file, the requestor found that, in comparison, when reported as a secondary diagnosis, ICD-10-CM diagnosis code O63.9 (Long labor, unspecified), which is designated as a CC, had a C1 value of only 0.88. The requestor also performed an analysis of claims at their healthcare facility to identify cases where prolonged labor in either the latent phase or second phase likely occurred and found that the C1 value was approximately 1.35 for diagnosis code O63.0. The requestor did not state if the analysis of cases at their facility was limited to Medicare cases.

We agree that that diagnosis code O63.0 (Prolonged first stage (of labor)) is currently designated as a NonCC and diagnosis code O63.9 (Long labor, unspecified) is currently designated as a CC. We refer the reader to Appendix G of the ICD-10 MS-DRG Version 43.1 Definitions Manual (available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drug-classifications-and-software>) for the complete list of diagnoses designated as CCs when reported as secondary diagnoses, except when used in conjunction with the principal diagnosis in the corresponding CC Exclusion List in Appendix C.

To evaluate this request, we analyzed the claims data in the September 2025 update of the FY 2025 MedPAR file. The following table shows the analysis for diagnosis codes O63.0 and O63.9.



| ICD-10-CM Code <sup>a</sup> | Description <sup>b</sup>         | Total Count <sup>c</sup> | Cnt1 <sup>d</sup> | C1 <sup>e</sup> | Cnt2 <sup>f</sup> | C2 <sup>g</sup> | Cnt3 <sup>h</sup> | C3 <sup>i</sup> |
|-----------------------------|----------------------------------|--------------------------|-------------------|-----------------|-------------------|-----------------|-------------------|-----------------|
| O63.0                       | Prolonged first stage (of labor) | 17                       | 6                 | 2.14            | 9                 | 3.54            | 2                 | 3.10            |
| O63.9                       | Long labor, unspecified          | 6                        | -                 | -               | 3                 | 1.54            | 3                 | 2.78            |

<sup>a</sup> This column is the secondary diagnosis code (SDX).

<sup>b</sup> This column is the title of the SDX.

<sup>c</sup> The total count of discharge claims with the SDX.

<sup>d</sup> Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.

<sup>e</sup> "C1" impact on resource use of the SDX for discharge claims in "Cnt1".

<sup>f</sup> Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.

<sup>g</sup> "C2" impact on resource use of the SDX for discharge claims in "Cnt2".

<sup>h</sup> Count of discharge claims with the SDX and with at least one other SDX that is a MCC.

<sup>i</sup> "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

We analyzed these data as described in the FY 2008 IPPS final rule (72 FR 47158 through 47161). The table shows that the C1 value of the diagnosis code that describes prolonged first stage of labor is 2.14. As stated earlier, a C1 value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C2 finding of diagnosis code O63.0 is 3.54. C2 values close to 3.0 suggests the condition is more similar to an MCC than a CC or non-CC. The C1 and C2 findings reflect increased resource utilization when prolonged labor is reported as a secondary diagnosis however the data are clearly mixed between the C1 and C2 findings, and there was a low volume of cases (17) reporting this code as a secondary diagnosis.

The table also shows there were zero cases that reported diagnosis code O63.9 with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 finding of diagnosis code O63.9 is 1.54. C2 values close to 2.0 suggest the condition is more similar to a CC than a non-CC. The C2 findings support maintaining diagnosis code O63.9 as a CC. Similar to diagnosis code O63.0, there was a low volume of cases (6) reporting this code as a secondary diagnosis.

In considering the nine guiding principles, as summarized previously, we note that the first stage of labor is defined as the interval between the onset of labor and complete or 10 cm cervical dilation. Prolonged first stage of labor refers to a slow initial dilation (0–6 cm), or a stalled active phase, lasting over 16–20 hours, whereas "long labor" describes the entire birth process exceeding 20–25 hours. Long labor is monitored closely for risks like infection or fetal distress. While a prolonged first stage is rarely dangerous, a prolonged first stage of labor can sometimes require a higher level of care. Management of prolonged first stage of labor can sometimes involve amniotomy for patients undergoing augmentation or induction of labor to reduce the

duration of labor, administration of oxytocin and/or the use intrauterine pressure catheters to determine adequacy of uterine contractions. If labor fails to progress or fetal distress occurs, a cesarean section or instrumental delivery (forceps/vacuum) may be necessary.

After considering the C1, and C2 values of ICD–10–CM diagnosis codes O63.0 and O63.9, the lack of sufficient claims data to support a severity level change, and consideration of the nine guiding principles, we believe diagnosis code O63.0 should remain designated as a NonCC and diagnosis code O63.9 should remain designated as a CC. Therefore, we are proposing to maintain the severity level designations of ICD–10–CM diagnosis codes O63.0 and O63.9 for FY 2027. We will continue to monitor the claims data in consideration of any future modifications to the severity level designation of diagnosis codes O63.0 and O63.9.

d. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2027

The following tables identify the proposed additions to the diagnosis code MCC severity level list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2027 and are available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> Table 6I.1—Proposed Additions to the MCC List—FY 2027; Table 6J.1—Proposed Additions to the CC List—FY 2027; and Table 6J.2—Proposed Deletions to the CC List—FY 2027

e. Proposed CC Exclusions List for FY 2027

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPE logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular

principal diagnosis. We created the CC Exclusions List for the following reasons: (1) to preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18886) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 43.1 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual (available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/>

*ms-drg-classifications-and-software*) and includes three lists identified as Part 1, Part 2 and Part 3. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as an MCC only for patients discharged alive; otherwise, they are assigned as a NonCC. Part 3 is the list of diagnosis codes that are designated as a CC or MCC and included in the definition of the logic for the listed MS-DRGs. When reported as a secondary diagnosis and grouped to one of the listed MS-DRGs, the diagnosis is excluded from acting as a CC/MCC for severity in DRG assignment (that is, suppression logic).

We are proposing changes to the ICD-10 MS-DRGs Version 44 CC Exclusion List based on the diagnosis code updates as discussed in section II.C.13. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule. Therefore, we have developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2027; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2027; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2027; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2027. For Table 6G.1, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses proposed to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions proposed for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code proposed for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the proposed deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Tables 6G.1., 6G.2., 6H.1.,

and 6H.2. associated with this FY 2027 IPPS/LTCH PPS proposed rule are available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>.

### 13. Proposed Changes to the ICD-10-CM and ICD-10-PCS Coding Systems

To identify new, revised, and deleted diagnosis and procedure codes, for FY 2027, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, and Table 6E.—Revised Diagnosis Code Titles for this FY 2027 IPPS/LTCH PPS proposed rule.

These tables are not published in the Addendum to this FY 2027 IPPS/LTCH PPS proposed rule, but are available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> as described in section VI. of the Addendum to this FY 2027 IPPS/LTCH PPS proposed rule. As discussed in section II.C.11. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, the code titles are adopted as part of the ICD-10 Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

We are proposing the MDC and MS-DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new procedure codes are set forth in Table 6B. Consistent with our established process, we examined the MS-DRG assignment and the attributes (severity level and O.R. status) of the predecessor diagnosis or procedure code, as applicable, to inform our proposed assignments and designations.

Specifically, we review the predecessor code and MS-DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS-DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We note that this process does not automatically result in the new diagnosis or procedure code being proposed for assignment to the same

MS-DRG or to have the same designation as the predecessor code.

We are making available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> the following tables associated with this FY 2027 IPPS/LTCH PPS proposed rule:

- Table 6A.—New Diagnosis Codes—FY 2027;
- Table 6B.—New Procedure Codes—FY 2027;
- Table 6C.—Invalid Diagnosis Codes—FY 2027;
- Table 6D.—Invalid Procedure Codes—FY 2027;
- Table 6E.—Revised Diagnosis Code Titles—FY 2027;
- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2027;
- Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2027;
- Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2027;
- Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2027;
- Table 6I.1.—Proposed Additions to the MCC List—FY 2027;
- Table 6J.1.—Proposed Additions to the CC List—FY 2027; and
- Table 6J.2.—Proposed Deletions to the CC List—FY 2027.

### 14. Proposed Changes to the Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS-DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPE by which cases with multiple surgical procedures are assigned to a single MS-DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS-DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS-DRGs. For example, in MDC 11, the surgical class “kidney transplant” consists of a single MS-DRG (MS-DRG 652) and the class “major bladder procedures” consists of three MS-DRGs (MS-DRGs 653, 654, and 655).

Consequently, in many cases, the surgical hierarchy has an impact on more than one MS-DRG. The

methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS-DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS-DRGs 001 and 002 and surgical class B includes MS-DRGs 003, 004, and 005. Assume also that the average costs of MS-DRG 001 are higher than that of MS-DRG 003, but the average costs of MS-DRGs 004 and 005 are higher than the average costs of MS-DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS-DRG in the class by frequency (that is, by the number of cases in the MS-DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of “other O.R. procedures” as discussed in this FY 2027 IPPS/LTCH PPS proposed rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS-DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical

hierarchy provides that the GROUPE search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the “other O.R. procedures” surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS-DRG or MS-DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The “other O.R. procedures” class is a group of procedures that are only infrequently related to the diagnoses in the MDC but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift, such that the higher-

ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we are proposing to make for FY 2027, as discussed in section II.C. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, our proposal for Appendix D MS-DRG Surgical Hierarchy by MDC and MS-DRG of the proposed ICD-10 MS-DRG Definitions Manual Version 44 to modify the existing surgical hierarchy in the Pre-MDC, MDC 05, MDC 08, MDC 10, MDC 11, MDC 12, and MDC 13 MS-DRGs for FY 2027 is illustrated in the following tables. We note that because the current methodology involves weighing the average costs of each MS-DRG in the surgical class by frequency (that is, by the number of cases in the MS-DRG) to determine average resource consumption for the surgical class, that the surgical hierarchy of other MS-DRGs in the MDC may need to be adjusted based on the MS-DRG classification changes that are proposed to ensure that the average weighted cost for each base MS-DRG in each MDC are monotonically decreasing. We further note that the proposed Version 44 surgical hierarchy as illustrated in the following tables may be subject to further modifications based on the finalized changes to the MS-DRG classifications for FY 2027.

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| PRE-MDC         |                                                                                                                      |                                                |                                                 |
|-----------------|----------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------|
|                 |                                                                                                                      | Current<br>Version 43<br>Surgical<br>Hierarchy | Proposed<br>Version 44<br>Surgical<br>Hierarchy |
| MS-DRG 018      | Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies                                                     | 1                                              | 1                                               |
| MS-DRGs 001-002 | Heart Transplant or Implant of Heart Assist System                                                                   | 2                                              | 2                                               |
| MS-DRG 003      | ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures | 3                                              | 3                                               |
| MS-DRG 004      | Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures      | 4                                              | 5                                               |
| MS-DRG 007      | Lung Transplant                                                                                                      | 5                                              | 4                                               |
| MS-DRG 014      | Allogeneic Bone Marrow Transplant                                                                                    | 6                                              | 6                                               |
| MS-DRGs 005-006 | Liver Transplant or Intestinal Transplant                                                                            | 7                                              | 7                                               |
| MS-DRG 019      | Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis                                            | 8                                              | 9                                               |
| MS-DRG 008      | Simultaneous Pancreas, Islet Cell and Kidney Transplant                                                              | 9                                              | 11                                              |
| MS-DRGs 016-017 | Autologous Bone Marrow Transplant                                                                                    | 10                                             | 10                                              |
| MS-DRG 010      | Pancreas or Islet Cell Transplant                                                                                    | 11                                             | 8                                               |
| MS-DRGs 011-013 | Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy                                                      | 12                                             | 12                                              |

| <b>MDC 05 (DISEASES AND DISORDERS OF THE CIRCULATORY SYSTEM)</b> |                                                                                         |                                                          |                                                           |
|------------------------------------------------------------------|-----------------------------------------------------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------|
|                                                                  |                                                                                         | <b>Current<br/>Version 43<br/>Surgical<br/>Hierarchy</b> | <b>Proposed<br/>Version 44<br/>Surgical<br/>Hierarchy</b> |
| MS-DRG 209                                                       | Complex Aortic Arch Procedures                                                          | 1                                                        | 1                                                         |
| MS-DRG 212                                                       | Concomitant Aortic and Mitral Valve Procedures                                          | 2                                                        | 2                                                         |
| MS-DRG 215                                                       | Other Heart Assist System Implant                                                       | 3                                                        | 3                                                         |
| MS-DRGs 216-218                                                  | Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization    | 4                                                        | 4                                                         |
| MS-DRGs 231-232                                                  | Coronary Bypass with PTCA                                                               | 5                                                        | 5                                                         |
| MS-DRG 275                                                       | Cardiac Defibrillator Implant with Cardiac Catheterization                              | 6                                                        | 6                                                         |
| MS-DRG 317                                                       | Concomitant Left Atrial Appendage Closure and Cardiac Ablation                          | 7                                                        | 7                                                         |
| MS-DRGs 219-221                                                  | Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization | 8                                                        | 8                                                         |
| MS-DRGs 233-234                                                  | Coronary Bypass with Cardiac Catheterization or Open Ablation                           | 9                                                        | 9                                                         |
| MS-DRG 213                                                       | Endovascular Abdominal Aorta with Iliac Branch Procedures                               | 10                                                       | 10                                                        |
| MS-DRGs 266-267                                                  | Endovascular Cardiac Valve Replacement and Supplement Procedures                        | 11                                                       | 12                                                        |
| MS-DRGs 276-277                                                  | Cardiac Defibrillator Implant                                                           | 12                                                       | 11                                                        |
| MS-DRGs 268-269                                                  | Aortic and Heart Assist Procedures Except Pulsation Balloon                             | 13                                                       | 13                                                        |
| MS-DRGs 235-236                                                  | Coronary Bypass without Cardiac Catheterization                                         | 14                                                       | 14                                                        |
| MS-DRG 245                                                       | AICD Generator Procedures                                                               | 15                                                       | 15                                                        |
| MS-DRGs 270-272                                                  | Other Major Cardiovascular Procedures                                                   | 16                                                       | 17                                                        |
| MS-DRGs 228-229                                                  | Other Cardiothoracic Procedures                                                         | 17                                                       | 18                                                        |
| MS-DRGs 319-320                                                  | Other Endovascular Cardiac Valve Procedures                                             | 18                                                       | 20                                                        |
| MS-DRGs 278-279                                                  | Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures         | 19                                                       | 16                                                        |
| MS-DRGs 323-324                                                  | Coronary Intravascular Lithotripsy with Intraluminal Device                             | 20                                                       | 19                                                        |
| MS-DRGs 239-241                                                  | Amputation for Circulatory System Disorders Except Upper Limb and Toe                   | 21                                                       | 21                                                        |
| MS-DRG 265                                                       | AICD Lead Procedures                                                                    | 22                                                       | 25                                                        |
| MS-DRGs 273-274                                                  | Percutaneous and Other Intracardiac Procedures                                          | 23                                                       | 22                                                        |
| MS-DRG 325                                                       | Coronary Intravascular Lithotripsy without Intraluminal Device                          | 24                                                       | 23                                                        |
| MS-DRG 263                                                       | Vein Ligation and Stripping                                                             | 25                                                       | 24                                                        |
| MS-DRGs 252-254                                                  | Other Vascular Procedures                                                               | 26                                                       | 26                                                        |
| MS-DRGs 359-360                                                  | Percutaneous Coronary Atherectomy with Intraluminal Device                              | 27                                                       | 27                                                        |
| MS-DRGs 242-244                                                  | Permanent Cardiac Pacemaker Implant                                                     | 28                                                       | 29                                                        |
| Proposed New MS-DRGs 210-211                                     | Cardiac Pacemaker Revision or Device Replacement                                        | N/A                                                      | 30                                                        |
| MS-DRG 318                                                       | Percutaneous Coronary Atherectomy without Intraluminal Device                           | 30                                                       | 28                                                        |
| MS-DRGs 321-322                                                  | Percutaneous Cardiovascular Procedures with Intraluminal Device                         | 31                                                       | 31                                                        |
| MS-DRGs 255-257                                                  | Upper Limb and Toe Amputation for Circulatory System Disorders                          | 32                                                       | 32                                                        |
| MS-DRGs 250-251                                                  | Percutaneous Cardiovascular Procedures without Intraluminal Device                      | 33                                                       | 33                                                        |
| Proposed New MS-DRGs 361-362                                     | Other Circulatory System O.R. Procedures                                                | N/A                                                      | 34                                                        |

| <b>MDC 08 (DISEASES AND DISORDERS OF THE MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE)</b> |                                                                                                    |                                                          |                                                           |
|--------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------|
|                                                                                            |                                                                                                    | <b>Current<br/>Version 43<br/>Surgical<br/>Hierarchy</b> | <b>Proposed<br/>Version 44<br/>Surgical<br/>Hierarchy</b> |
| Proposed New<br>MS-DRGs 523-525                                                            | Extensive or Complex Spinal Fusion Procedures Except Cervical                                      | N/A                                                      | <b>1</b>                                                  |
| MS-DRGs 426-428                                                                            | Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical                       | 2                                                        | 2                                                         |
| MS-DRGs 429-430                                                                            | Combined Anterior and Posterior Cervical Spinal Fusion                                             | 3                                                        | 3                                                         |
| MS-DRGs 456-458                                                                            | Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection                      | 4                                                        | 4                                                         |
| MS-DRGs 447-448                                                                            | Multiple Level Spinal Fusion Except Cervical                                                       | 5                                                        | 5                                                         |
| Proposed New<br>MS-DRGs 403-404                                                            | Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection                  | N/A                                                      | <b>8</b>                                                  |
| MS-DRG 402                                                                                 | Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical                         | 7                                                        | 6                                                         |
| MS-DRGs 463-465                                                                            | Wound Debridement or Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders    | 8                                                        | 11                                                        |
| MS-DRGs 450-451                                                                            | Single Level Spinal Fusion Except Cervical                                                         | 9                                                        | 9                                                         |
| Proposed New<br>MS-DRG 449                                                                 | Revision of Hip or Knee Replacement                                                                | N/A                                                      | <b>7</b>                                                  |
| MS-DRGs 461-462                                                                            | Bilateral or Multiple Major Joint Procedures of Lower Extremity                                    | 11                                                       | <b>12</b>                                                 |
| MS-DRGs 471-473                                                                            | Cervical Spinal Fusion                                                                             | 12                                                       | 10                                                        |
| MS-DRGs 474-476                                                                            | Amputation for Musculoskeletal System and Connective Tissue Disorders                              | 13                                                       | 15                                                        |
| MS-DRG 483                                                                                 | Major Joint or Limb Reattachment Procedures of Upper Extremities                                   | 14                                                       | <b>14</b>                                                 |
| MS-DRGs 477-479                                                                            | Biopsies of Musculoskeletal System and Connective Tissue                                           | 15                                                       | <b>16</b>                                                 |
| MS-DRGs 492-494                                                                            | Lower Extremity and Humerus Procedures Except Hip, Foot and Femur                                  | 16                                                       | 17                                                        |
| MS-DRGs 498-499                                                                            | Local Excision and Removal of Internal Fixation Devices of Hip and Femur                           | 17                                                       | <b>13</b>                                                 |
| Proposed New<br>MS-DRGs 400-401                                                            | Knee Procedures with Principal Diagnosis of Infection                                              | N/A                                                      | <b>24</b>                                                 |
| MS-DRGs 521-522                                                                            | Hip Replacement with Principal Diagnosis of Hip Fracture                                           | 19                                                       | 18                                                        |
| MS-DRGs 480-482                                                                            | Hip and Femur Procedures Except Major Joint                                                        | 20                                                       | 19                                                        |
| MS-DRGs 518-520                                                                            | Back and Neck Procedures Except Spinal Fusion or Disc Device or Neurostimulator                    | <b>21</b>                                                | 20                                                        |
| MS-DRGs 469-470                                                                            | Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity or Total Ankle Replacement | 22                                                       | 22                                                        |
| MS-DRGs 510-512                                                                            | Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures                               | 23                                                       | 21                                                        |
| MS-DRGs 503-505                                                                            | Foot Procedures                                                                                    | <b>24</b>                                                | 25                                                        |
| MS-DRGs 500-502                                                                            | Soft Tissue Procedures                                                                             | 25                                                       | 23                                                        |
| MS-DRGs 495-497                                                                            | Local Excision and Removal of Internal Fixation Devices Except Hip and Femur                       | 26                                                       | 27                                                        |
| MS-DRGs 507-508                                                                            | Major Shoulder or Elbow Joint Procedures                                                           | 27                                                       | 28                                                        |
| MS-DRGs 488-489                                                                            | Knee Procedures without Principal Diagnosis of Infection                                           | 28                                                       | 26                                                        |
| MS-DRGs 513-514                                                                            | Hand or Wrist Procedures, Except Major Thumb or Joint Procedures                                   | 29                                                       | 29                                                        |
| MS-DRG 506                                                                                 | Major Thumb or Joint Procedures                                                                    | 30                                                       | 30                                                        |
| MS-DRGs 515-517                                                                            | Other Musculoskeletal System and Connective Tissue O.R. Procedures                                 | 31                                                       | 31                                                        |

| <b>MDC 10 (ENDOCRINE, NUTRITIONAL AND METABOLIC DISEASES AND DISORDERS)</b> |                                                                                      |                                                          |                                                           |
|-----------------------------------------------------------------------------|--------------------------------------------------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------|
|                                                                             |                                                                                      | <b>Current<br/>Version 43<br/>Surgical<br/>Hierarchy</b> | <b>Proposed<br/>Version 44<br/>Surgical<br/>Hierarchy</b> |
| MS-DRGs 616-618                                                             | Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders          | 1                                                        | 2                                                         |
| MS-DRGs 619-621                                                             | O.R. Procedures for Obesity                                                          | 2                                                        | 5                                                         |
| MS-DRGs 614-615                                                             | Adrenal and Pituitary Procedures                                                     | 3                                                        | 3                                                         |
| MS-DRGs 622-624                                                             | Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders | 4                                                        | 1                                                         |
| MS-DRGs 625-627                                                             | Thyroid, Parathyroid and Thyroglossal Procedures                                     | 5                                                        | 4                                                         |
| MS-DRGs 628-630                                                             | Other Endocrine, Nutritional and Metabolic O.R. Procedures                           | 6                                                        | 6                                                         |

| <b>MDC 11 (DISEASES AND DISORDERS OF THE KIDNEY AND URINARY TRACT)</b> |                                               |                                                          |                                                           |
|------------------------------------------------------------------------|-----------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------|
|                                                                        |                                               | <b>Current<br/>Version 43<br/>Surgical<br/>Hierarchy</b> | <b>Proposed<br/>Version 44<br/>Surgical<br/>Hierarchy</b> |
| MS-DRGs 650-651                                                        | Kidney Transplant with Hemodialysis           | 1                                                        | 1                                                         |
| MS-DRG 652                                                             | Kidney Transplant                             | 2                                                        | 3                                                         |
| MS-DRGs 653-655                                                        | Major Bladder Procedures                      | 3                                                        | 2                                                         |
| MS-DRGs 656-658                                                        | Kidney and Ureter Procedures for Neoplasm     | 4                                                        | 5                                                         |
| MS-DRGs 659-661                                                        | Kidney and Ureter Procedures for Non-Neoplasm | 5                                                        | 9                                                         |
| MS-DRGs 662-664                                                        | Minor Bladder Procedures                      | 6                                                        | 6                                                         |
| MS-DRGs 665-667                                                        | Prostatectomy                                 | 7                                                        | 4                                                         |
| MS-DRGs 668-670                                                        | Transurethral Procedures                      | 8                                                        | 7                                                         |
| MS-DRGs 671-672                                                        | Urethral Procedures                           | 9                                                        | 8                                                         |
| MS-DRGs 673-675                                                        | Other Kidney and Urinary Tract Procedures     | 10                                                       | 10                                                        |

| <b>MDC 12 (DISEASES AND DISORDERS OF THE MALE REPRODUCTIVE SYSTEM)</b> |                                                                   |                                                          |                                                           |
|------------------------------------------------------------------------|-------------------------------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------|
|                                                                        |                                                                   | <b>Current<br/>Version 43<br/>Surgical<br/>Hierarchy</b> | <b>Proposed<br/>Version 44<br/>Surgical<br/>Hierarchy</b> |
| MS-DRGs 707-708                                                        | Major Male Pelvic Procedures                                      | 1                                                        | 4                                                         |
| MS-DRGs 709-710                                                        | Penis Procedures                                                  | 2                                                        | 2                                                         |
| MS-DRGs 711-712                                                        | Testes Procedures                                                 | 3                                                        | 3                                                         |
| MS-DRGs 713-714                                                        | Transurethral Prostatectomy                                       | 4                                                        | 5                                                         |
| MS-DRGs 715-716                                                        | Male Reproductive System and Other O.R. Procedures for Malignancy | 5                                                        | 1                                                         |
| MS-DRGs 717-718                                                        | Other Male Reproductive System O.R. Procedures                    | 6                                                        | 6                                                         |

For issues pertaining to the surgical hierarchy, as with other MS-DRG related requests, we encourage interested parties to submit comments no later than October 20, 2026, via MEARIS™ at <https://mearis.cms.gov/public/home>, so that they can be considered for possible inclusion in the annual proposed rule.

#### 15. Maintenance of the ICD-10-CM and ICD-10-PCS Coding Systems

In September 1985, the ICD-9-CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD-9-CM system. The final update to ICD-9-CM codes was made on October 1, 2013. Thereafter,

the name of the Committee was changed to the ICD-10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD-10 Coordination and Maintenance Committee addresses updates to the ICD-10-CM and ICD-10-PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly identified diseases and newly

developed procedures and technologies.  
The Committee is also responsible for  
encouraging the use of Federal and non-

Federal educational programs and  
employing other communication  
techniques with a view toward

standardizing coding applications and  
upgrading the quality of the  
classification system.

| MDC 13 (DISEASES AND DISORDERS OF THE FEMALE REPRODUCTIVE SYSTEM) |                                                                  |                                                |                                                 |
|-------------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------|
|                                                                   |                                                                  | Current<br>Version 43<br>Surgical<br>Hierarchy | Proposed<br>Version 44<br>Surgical<br>Hierarchy |
| MS-DRGs 734-735                                                   | Pelvic Evisceration, Radical Hysterectomy and Radical Vulvectomy | 1                                              | 2                                               |
| Proposed New<br>MS-DRGs 731-733                                   | Uterine and Adnexa Procedures for Malignancy                     | N/A                                            | 1                                               |
| MS-DRGs 742-743                                                   | Uterine and Adnexa Procedures for Non-Malignancy                 | 3                                              | 4                                               |
| MS-DRGs 744-745                                                   | D&C, Conization, Laparoscopy and Tubal Interruption              | 4                                              | 3                                               |
| MS-DRGs 746-747                                                   | Vagina, Cervix and Vulva Procedures                              | 5                                              | 6                                               |
| MS-DRG 748                                                        | Female Reproductive System Reconstructive Procedures             | 6                                              | 5                                               |
| MS-DRGs 749-750                                                   | Other Female Reproductive System O.R. Procedures                 | 7                                              | 7                                               |

| Procedure Code | Description                                                                        | O.R. | MDC | MS-DRG  |
|----------------|------------------------------------------------------------------------------------|------|-----|---------|
| 02HM3JZ**      | Insertion of pacemaker lead into ventricular septum, percutaneous approach         | N    | 01  | 040-042 |
|                |                                                                                    |      | 05  | 260-262 |
|                |                                                                                    |      | 21  | 907-909 |
|                |                                                                                    |      | 24  | 957-959 |
| 02HM3KZ        | Insertion of defibrillator lead into ventricular septum, percutaneous approach     | Y    | 05  | 265     |
|                |                                                                                    |      | 14  | 768-769 |
|                |                                                                                    |      |     | 817-819 |
|                |                                                                                    |      | 17  | 823-825 |
|                |                                                                                    |      |     | 829-830 |
|                |                                                                                    |      |     | 850     |
|                |                                                                                    |      | 18  | 853-855 |
|                |                                                                                    |      |     | 856-858 |
|                |                                                                                    |      | 19  | 876     |
|                |                                                                                    |      | 23  | 939-941 |
|                |                                                                                    |      | 25  | 969-970 |
| 02HM3MZ**      | Insertion of cardiac lead into ventricular septum, percutaneous approach           | N    | 05  | 260-262 |
| 02HM3NZ        | Insertion of intracardiac pacemaker into ventricular septum, percutaneous approach | Y    | 05  | 228-229 |
|                |                                                                                    |      | 14  | 768-769 |
|                |                                                                                    |      |     | 817-819 |
|                |                                                                                    |      | 17  | 823-825 |
|                |                                                                                    |      |     | 829-830 |
|                |                                                                                    |      |     | 850     |
|                |                                                                                    |      | 18  | 853-855 |
|                |                                                                                    |      |     | 856-858 |
|                |                                                                                    |      | 19  | 876     |
|                |                                                                                    |      | 23  | 939-941 |
|                |                                                                                    |      | 25  | 969-970 |
| 02HM3YZ        | Insertion of other device into ventricular septum, percutaneous approach           | Y    | 05  | 260-262 |
|                |                                                                                    |      | 14  | 768-769 |
|                |                                                                                    |      |     | 817-819 |
|                |                                                                                    |      | 17  | 823-825 |
|                |                                                                                    |      |     | 829-830 |
|                |                                                                                    |      |     | 850     |
|                |                                                                                    |      | 18  | 853-855 |
|                |                                                                                    |      |     | 856-858 |
|                |                                                                                    |      | 19  | 876     |
|                |                                                                                    |      | 23  | 939-941 |
|                |                                                                                    |      | 25  | 969-970 |
| 0DDU0ZZ        | Extraction of omentum, open approach                                               | Y    | 06  | 356-358 |
|                |                                                                                    |      | 07  | 423-425 |
|                |                                                                                    |      | 10  | 628-630 |
|                |                                                                                    |      | 13  | 749-750 |
|                |                                                                                    |      | 14  | 768-769 |
|                |                                                                                    |      |     | 817-819 |
|                |                                                                                    |      | 17  | 820-822 |
|                |                                                                                    |      |     | 826-828 |
|                |                                                                                    |      | 18  | 853-855 |
|                |                                                                                    |      |     | 856-858 |
|                |                                                                                    |      | 19  | 876     |
|                |                                                                                    |      | 23  | 939-941 |
| 0DDU4ZZ        | Extraction of omentum, percutaneous endoscopic approach                            | Y    | 06  | 356-358 |
|                |                                                                                    |      | 07  | 423-425 |
|                |                                                                                    |      | 10  | 628-630 |
|                |                                                                                    |      | 13  | 749-750 |
|                |                                                                                    |      | 14  | 768-769 |
|                |                                                                                    |      |     | 817-819 |
|                |                                                                                    |      | 17  | 820-822 |
|                |                                                                                    |      |     | 826-828 |
|                |                                                                                    |      | 18  | 853-855 |
|                |                                                                                    |      |     | 856-858 |
|                |                                                                                    |      | 19  | 876     |
|                |                                                                                    |      | 23  | 939-941 |

## BILLING CODE 4120-01-C

The official list of ICD-9-CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: <https://www.cms.gov/medicare/>

*coding-billing/icd-10-codes/icd-9-cm-diagnosis-procedure-codes-abbreviated-and-full-code-titles.*

The official list of ICD-10-CM and ICD-10-PCS codes can be found on the

CMS website at: <http://www.cms.gov/Medicare/Coding/ICD10/index.html>.

The NCHS has lead responsibility for the ICD-10-CM and ICD-9-CM diagnosis codes included in the Tabular



List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD-10-PCS and ICD-9-CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages health-related organizations to participate in the previously mentioned process. In this regard, the Committee makes code request materials and proposed coding changes publicly available. These materials provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. Members of the public may submit comments on the proposed procedure code topics to CMS at: [ICDProcedureCodeRequest@cms.hhs.gov](mailto:ICDProcedureCodeRequest@cms.hhs.gov) and may submit comments on the proposed diagnosis code topics to the CDC/NCHS at: [nchsICD-10-CM@cdc.gov](mailto:nchsICD-10-CM@cdc.gov). After considering the public comments submitted, the Committee formulates recommendations, which then must be approved by CDC/NCHS and CMS.

The Committee presented proposals for ICD-10-CM diagnosis code changes for implementation in FY 2027 at the virtual public meetings held on September 9–10, 2025 and finalized the coding changes after consideration of comments received during the meetings and in writing by November 14, 2025.

In lieu of CMS holding its Fall 2025 meeting, the Committee solicited comments on the Fall 2025 ICD-10-PCS procedure code topics. The deadline to submit comments on the procedure code proposals considered for an April 1, 2026 implementation was October 10, 2025, and the deadline to submit comments on the procedure code

proposals being considered for an October 1, 2026 implementation was November 14, 2025.

The Committee presented proposals for ICD-10-CM diagnosis code changes for implementation in FY 2027 and FY 2028 at the virtual public meetings held on March 17–18, 2026 and will finalize the coding changes after consideration of comments received during the meetings and in writing by May 15, 2026.

In lieu of CMS holding its Spring 2026 meeting, the Committee solicited comments on the Spring 2026 ICD-10-PCS procedure code topics. The deadline for submitting public comments on these code proposals is April 17, 2026. The Committee will review the public comments submitted and identify whether there is a consensus of support for any new diagnosis and procedure codes. The Committee will also determine those new procedure codes for which complete tabular and indexing changes can be made by June 2026 and will include those in the October 1, 2026 update to the ICD-10-CM diagnosis and ICD-10-PCS procedure code sets. As discussed in earlier sections of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, there are new, revised, and deleted ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, and Table 6E.—Revised Diagnosis Code Titles for this FY 2027 IPPS/LTCH PPS proposed rule, which are available on the CMS website at: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps>.

The code titles are adopted as part of the ICD-10 Coordination and Maintenance Committee process. As previously noted, although we make the code titles available in association with the IPPS proposed rule, they are not

subject to comment in the proposed rule. Because of the length of these tables, they are not published in the Addendum to the proposed rule. Rather, they are available on the CMS website as discussed in section VI. of the Addendum to the proposed rule.

Recordings and materials for the virtual meeting discussions of the diagnosis codes at the Committee's September 9–10, 2025 meeting can be found at: <https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html>. Materials for the Fall 2025 ICD-10-PCS procedure code topics can be obtained from the CMS website at: <https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials>. These websites also provide detailed information about the Committee, including information on requesting a new code, participating in a Committee meeting, timeline requirements, submitting comments, and meeting dates.

We encourage commenters to submit questions and comments on coding issues involving diagnosis codes to CDC/NCHS via Email to: [nchsICD-10-CM@cdc.gov](mailto:nchsICD-10-CM@cdc.gov).

Questions and comments concerning the procedure codes should be submitted to CMS via Email to: [ICDProcedureCodeRequest@cms.hhs.gov](mailto:ICDProcedureCodeRequest@cms.hhs.gov).

CMS implemented 80 new procedure codes including codes to describe the insertion of cardiac devices, (*i.e.*, leads) into the ventricular septum, codes to enable the differentiation between the endoscopic techniques utilized to drain hepatobiliary and pancreatic fluid collections, and codes to capture the utilization of adjunctive therapies such as microcurrent electrical neuromuscular stimulation (MENS) and frequency-specific microcurrent (FSM) into the ICD-10-PCS classification effective with discharges on and after April 1, 2026. The procedure codes are as follows:

**BILLING CODE 4120-01-P**

|          |                                                                                                                          |   |    |         |
|----------|--------------------------------------------------------------------------------------------------------------------------|---|----|---------|
| 0DDV0ZZ  | Extraction of mesentery, open approach                                                                                   | Y | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
| 0DDV4ZZ  | Extraction of mesentery, percutaneous endoscopic approach                                                                | Y | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
| 0F9480D* | Drainage of gallbladder with drainage device, via natural or artificial opening endoscopic, transmural                   | N | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
| 0F9480F* | Drainage of gallbladder with drainage device, via natural or artificial opening endoscopic, transpapillary               | N | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
| 0F9580D* | Drainage of right hepatic duct with drainage device, via natural or artificial opening endoscopic, transmural            | N | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
| 0F9580E* | Drainage of right hepatic duct with drainage device, via natural or artificial opening endoscopic, transpapillary        | N | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
| 0F9680D* | Drainage of left hepatic duct with drainage device, via natural or artificial opening endoscopic, transmural             | N | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
| 0F9680E* | Drainage of left hepatic duct with drainage device, via natural or artificial opening endoscopic, transpapillary         | N | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
| 0F9780D* | Drainage of common hepatic duct with drainage device, via natural or artificial opening endoscopic, transmural           | N | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
| 0F9780E* | Drainage of common hepatic duct with drainage device, via natural or artificial opening endoscopic, transpapillary       | N | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
| 0F9880D* | Drainage of cystic duct with drainage device, via natural or artificial opening endoscopic, transmural                   | N | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
| 0F9880E* | Drainage of cystic duct with drainage device, via natural or artificial opening endoscopic, transpapillary               | N | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
| 0F9980D* | Drainage of common bile duct with drainage device, via natural or artificial opening endoscopic, transmural              | N | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
| 0F9980E* | Drainage of common bile duct with drainage device, via natural or artificial opening endoscopic, transpapillary          | N | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
| 0F9C80D* | Drainage of ampulla of Vater with drainage device, via natural or artificial opening endoscopic, transmural              | N | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
| 0F9C80E* | Drainage of ampulla of Vater with drainage device, via natural or artificial opening endoscopic, transpapillary          | N | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
| 0F9D80D* | Drainage of pancreatic duct with drainage device, via natural or artificial opening endoscopic, transmural               | N | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
| 0F9D80E* | Drainage of pancreatic duct with drainage device, via natural or artificial opening endoscopic, transpapillary           | N | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
| 0F9F80D* | Drainage of accessory pancreatic duct with drainage device, via natural or artificial opening endoscopic, transmural     | N | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
| 0F9F80E* | Drainage of accessory pancreatic duct with drainage device, via natural or artificial opening endoscopic, transpapillary | N | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
|          |                                                                                                                          |   | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
| 0F9G80D* | Drainage of pancreas with drainage device, via natural or artificial opening endoscopic, transmural                      | N | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |
|          |                                                                                                                          |   | 14 | 768-769 |
|          |                                                                                                                          |   |    | 817-819 |
| 0F9G80E* | Drainage of pancreas with drainage device, via natural or artificial opening endoscopic, transpapillary                  | N | 17 | 820-822 |
|          |                                                                                                                          |   |    | 826-828 |
|          |                                                                                                                          |   | 18 | 853-855 |
|          |                                                                                                                          |   | 18 | 856-858 |
|          |                                                                                                                          |   | 19 | 876     |
|          |                                                                                                                          |   | 23 | 939-941 |
|          |                                                                                                                          |   | 06 | 356-358 |
|          |                                                                                                                          |   | 07 | 423-425 |
|          |                                                                                                                          |   | 10 | 628-630 |
|          |                                                                                                                          |   | 13 | 749-750 |

|         |                                                                    |   |    |         |
|---------|--------------------------------------------------------------------|---|----|---------|
| 0TXB0Z6 | Transfer bladder to right ureter, open approach                    | Y | 11 | 656-658 |
|         |                                                                    |   | 14 | 659-661 |
|         |                                                                    |   | 17 | 768-769 |
|         |                                                                    |   |    | 817-819 |
|         |                                                                    |   |    | 823-825 |
|         |                                                                    |   |    | 829-830 |
|         |                                                                    |   |    | 850     |
|         |                                                                    |   | 18 | 853-855 |
|         |                                                                    |   |    | 856-858 |
| 0TXB0Z7 | Transfer bladder to left ureter, open approach                     | Y | 19 | 876     |
|         |                                                                    |   | 21 | 907-909 |
|         |                                                                    |   | 23 | 939-941 |
|         |                                                                    |   | 24 | 958-959 |
|         |                                                                    |   | 25 | 969-970 |
|         |                                                                    |   | 11 | 656-658 |
|         |                                                                    |   | 14 | 659-661 |
|         |                                                                    |   | 17 | 768-769 |
|         |                                                                    |   |    | 817-819 |
| 0TXB4Z6 | Transfer bladder to right ureter, percutaneous endoscopic approach | Y |    | 823-825 |
|         |                                                                    |   |    | 829-830 |
|         |                                                                    |   |    | 850     |
|         |                                                                    |   | 18 | 853-855 |
|         |                                                                    |   |    | 856-858 |
|         |                                                                    |   | 19 | 876     |
|         |                                                                    |   | 21 | 907-909 |
|         |                                                                    |   | 23 | 939-941 |
|         |                                                                    |   | 24 | 958-959 |
| 0TXB4Z7 | Transfer bladder to left ureter, percutaneous endoscopic approach  | Y | 25 | 969-970 |
|         |                                                                    |   | 11 | 656-658 |
|         |                                                                    |   | 14 | 659-661 |
|         |                                                                    |   | 17 | 768-769 |
|         |                                                                    |   |    | 817-819 |
|         |                                                                    |   |    | 823-825 |
|         |                                                                    |   |    | 829-830 |
|         |                                                                    |   |    | 850     |
|         |                                                                    |   | 18 | 853-855 |
| 0VT00ZE | Resection of prostate, open approach, capsule intact               | Y |    | 856-858 |
|         |                                                                    |   | 19 | 876     |
|         |                                                                    |   | 21 | 907-909 |
|         |                                                                    |   | 23 | 939-941 |
|         |                                                                    |   | 24 | 958-959 |
|         |                                                                    |   | 25 | 969-970 |
|         |                                                                    |   | 11 | 665-667 |
|         |                                                                    |   | 12 | 707-708 |
|         |                                                                    |   | 17 | 823-825 |
|         |                                                                    |   |    | 829-830 |
|         |                                                                    |   |    | 850     |
|         |                                                                    |   | 18 | 853-855 |
|         |                                                                    |   |    | 856-858 |
|         |                                                                    |   | 19 | 876     |
|         |                                                                    |   | 23 | 939-941 |
|         |                                                                    |   | 25 | 969-970 |
|         |                                                                    |   |    |         |
|         |                                                                    |   |    |         |

|           |                                                                                                                                     |   |                                                |                                                                                                               |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------|---|------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| 0VT04ZE   | Resection of prostate, percutaneous endoscopic approach, capsule intact                                                             | Y | 11<br>12<br>17<br><br>18<br>19<br>23           | 665-667<br>707-708<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941                       |
| 0VT07ZE   | Resection of prostate, via natural or artificial opening, capsule intact                                                            | Y | 11<br>12<br>17<br><br>18<br>19<br>23           | 665-667<br>713-714<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941                       |
| 0VT08ZE   | Resection of prostate, via natural or artificial opening endoscopic, capsule intact                                                 | Y | 11<br>12<br>17<br><br>18<br>19<br>23           | 665-667<br>713-714<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941                       |
| 3E033AZ*  | Introduction of embryonic stem cells into peripheral vein, percutaneous approach                                                    | N |                                                |                                                                                                               |
| 3E043AZ*  | Introduction of embryonic stem cells into central vein, percutaneous approach                                                       | N |                                                |                                                                                                               |
| 4A0FXEJ*  | Measurement of musculoskeletal body composition using air displacement plethysmography, external approach                           | N |                                                |                                                                                                               |
| 5A0221E   | Assistance with cardiac output using blood flow modulator, continuous                                                               | Y | 05<br>14<br><br>17<br><br>18<br>19<br>23<br>25 | 270-272<br>768-769<br>817-819<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941<br>969-970 |
| F07DYD0** | Electrotherapeutic treatment of integumentary system - head and neck using microcurrent stimulation                                 | N | 23                                             | 945-946                                                                                                       |
| F07EYD0** | Electrotherapeutic treatment of integumentary system - thorax / abdomen using microcurrent stimulation                              | N | 23                                             | 945-946                                                                                                       |
| F07FYD0** | Electrotherapeutic treatment of integumentary system - upper back / upper extremity using microcurrent stimulation                  | N | 23                                             | 945-946                                                                                                       |
| F07GYD0** | Electrotherapeutic treatment of integumentary system - lower back / lower extremity using microcurrent stimulation                  | N | 23                                             | 945-946                                                                                                       |
| F07HYD0** | Electrotherapeutic treatment of integumentary system - whole body using microcurrent stimulation                                    | N | 23                                             | 945-946                                                                                                       |
| F08E5AZ** | Wound management treatment of integumentary system - thorax / abdomen using negative pressure therapy                               | N | 23                                             | 945-946                                                                                                       |
| F08E5BZ** | Wound management treatment of integumentary system - thorax / abdomen using physical agents                                         | N | 23                                             | 945-946                                                                                                       |
| F08E5CZ** | Wound management treatment of integumentary system - thorax / abdomen using mechanical equipment                                    | N | 23                                             | 945-946                                                                                                       |
| F08E5DZ** | Wound management treatment of integumentary system - thorax / abdomen using electrotherapeutic equipment                            | N | 23                                             | 945-946                                                                                                       |
| F08E5EZ** | Wound management treatment of integumentary system - thorax / abdomen using orthosis                                                | N | 23                                             | 945-946                                                                                                       |
| F08E5FZ** | Wound management treatment of integumentary system - thorax / abdomen using assistive, adaptive, supportive or protective equipment | N | 23                                             | 945-946                                                                                                       |
| F08E5UZ** | Wound management treatment of integumentary system - thorax / abdomen using prosthesis                                              | N | 23                                             | 945-946                                                                                                       |

|           |                                                                                                                                                                  |   |                                                                                                    |                                                                                                                                                                                                                             |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| F08E5YZ** | Wound management treatment of integumentary system - thorax / abdomen using other equipment                                                                      | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| F08E5ZZ** | Wound management treatment of integumentary system - thorax / abdomen                                                                                            | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| F08P5AZ** | Wound management treatment of musculoskeletal system - thorax / abdomen using negative pressure therapy                                                          | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| F08P5BZ** | Wound management treatment of musculoskeletal system - thorax / abdomen using physical agents                                                                    | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| F08P5CZ** | Wound management treatment of musculoskeletal system - thorax / abdomen using mechanical equipment                                                               | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| F08P5DZ** | Wound management treatment of musculoskeletal system - thorax / abdomen using electrotherapeutic equipment                                                       | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| F08P5EZ** | Wound management treatment of musculoskeletal system - thorax / abdomen using orthosis                                                                           | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| F08P5FZ** | Wound management treatment of musculoskeletal system - thorax / abdomen using assistive, adaptive, supportive or protective equipment                            | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| F08P5UZ** | Wound management treatment of musculoskeletal system - thorax / abdomen using prosthesis                                                                         | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| F08P5YZ** | Wound management treatment of musculoskeletal system - thorax / abdomen using other equipment                                                                    | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| F08P5ZZ** | Wound management treatment of musculoskeletal system - thorax / abdomen                                                                                          | N | 23                                                                                                 | 945-946                                                                                                                                                                                                                     |
| X2723CB   | Dilation of inferior vena cava and ilio caval confluence with open-structure polymer lattice intraluminal device, percutaneous approach, new technology group 11 | Y | 01<br>04<br>05<br>06<br>07<br>08<br>09<br>10<br>11<br>14<br>17<br>18<br>19<br>21<br>23<br>24<br>25 | 037-039<br>166-168<br>252-254<br>356-358<br>423-425<br>515-517<br>579-581<br>628-630<br>673-675<br>768-769<br>817-819<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>907-909<br>939-941<br>957-959<br>969-970 |
| X2HM3GB   | Insertion of lumenless small-diameter defibrillator lead into ventricular septum, percutaneous approach, new technology group 11                                 | Y | 05<br>14<br>17<br>18<br>19<br>23<br>25                                                             | 265<br>768-769<br>817-819<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941<br>969-970                                                                                                                   |
| X2HV3GB   | Insertion of lumenless small-diameter defibrillator lead into right ventricle, percutaneous approach, new technology group 11                                    | Y | 05<br>14<br>17<br>18<br>19<br>23<br>25                                                             | 265<br>768-769<br>817-819<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941<br>969-970                                                                                                                   |

|                       |                                                                                                                                                          |   |                                        |                                                                                                               |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|---|----------------------------------------|---------------------------------------------------------------------------------------------------------------|
| X2K00FB               | Bypass inferior vena cava using autologous cell seeded tissue engineered resorbable scaffold to pulmonary artery, open approach, new technology group 11 | Y | 05<br>14<br>17<br>18<br>19<br>23<br>25 | 228-229<br>768-769<br>817-819<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941<br>969-970 |
| X2KG0FB               | Bypass hepatic vein using autologous cell seeded tissue engineered resorbable scaffold to pulmonary artery, open approach, new technology group 11       | Y | 05<br>14<br>17<br>18<br>19<br>23<br>25 | 228-229<br>768-769<br>817-819<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941<br>969-970 |
| X9HD01B               | Insertion of temporary infusion device into right inner ear, open approach, new technology group 11                                                      | Y | 03<br>14<br>17<br>18<br>19<br>23<br>25 | 143-145<br>768-769<br>817-819<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941<br>969-970 |
| X9HE01B               | Insertion of temporary infusion device into left inner ear, open approach, new technology group 11                                                       | Y | 03<br>14<br>17<br>18<br>19<br>23<br>25 | 143-145<br>768-769<br>817-819<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941<br>969-970 |
| X9HF01B               | Insertion of temporary infusion device into bilateral inner ear, open approach, new technology group 11                                                  | Y | 03<br>14<br>17<br>18<br>19<br>23<br>25 | 143-145<br>768-769<br>817-819<br>823-825<br>829-830<br>850<br>853-855<br>856-858<br>876<br>939-941<br>969-970 |
| XU7G71B <sup>†</sup>  | Dilation of vagina with temporary electromechanical intraluminal device, via natural or artificial opening, new technology group 11                      | N |                                        |                                                                                                               |
| XW0330B <sup>‡</sup>  | Introduction of alpha1-proteinase inhibitor into peripheral vein, percutaneous approach, new technology group 11                                         | N |                                        |                                                                                                               |
| XW0331B <sup>•*</sup> | Introduction of anitocabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 11                             | N | Pre-MDC                                | 018                                                                                                           |
| XW0430B <sup>*</sup>  | Introduction of alpha1-proteinase inhibitor into central vein, percutaneous approach, new technology group 11                                            | N |                                        |                                                                                                               |
| XW0431B <sup>•*</sup> | Introduction of anitocabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 11                                | N | Pre-MDC                                | 018                                                                                                           |
| XW0534B <sup>*</sup>  | Introduction of somatic stem cells into peripheral artery, percutaneous approach, new technology group 11                                                | N |                                        |                                                                                                               |
| XW0632B <sup>§</sup>  | Introduction of CPT-601 enzyme replacement therapy into cerebral ventricle, percutaneous approach, new technology group 11                               | N |                                        |                                                                                                               |
| XW0E33B <sup>*</sup>  | Introduction of DB-O1O via intracochlear infusion into ear(s), percutaneous approach, new technology group 11                                            | N |                                        |                                                                                                               |

\*As the procedure codes are designated as non-O.R. procedures, there is no assigned MDC or MS-DRG. The ICD-10 MS-DRG assignment is dependent on the reported principal diagnosis, any secondary diagnoses defined as a complication or comorbidity (CC) or major complication or comorbidity (MCC), procedures or services performed, age, sex, and discharge status.

\*\*Non-O.R. procedure affecting the MS-DRG assignment.

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The 80 procedure codes are also reflected in Table 6B.- New Procedure Codes, which is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS>. As with the other new procedure codes and MS-DRG assignments included in Table 6B in association with this FY 2027 IPPS/LTCH PPS proposed rule, we are inviting public comments on the most appropriate MDC, MS-DRG, and operating room status assignments for these codes for FY 2027, as well as any other options for the Grouper logic.

We note that Change Request (CR) 14337, Transmittal 13562, titled “April 2026 Update to the Medicare Severity-Diagnosis Related Group (MS-DRG) Grouper and Medicare Code Editor (MCE) Version V43.1” was issued on December 23, 2025 (available on the CMS website at: <https://www.cms.gov/medicare/regulations-guidance/transmittals/2025-transmittals/r13562cp>) regarding the release of an updated version of the ICD-10 MS-DRG Grouper and Medicare Code Editor software, Version V43.1, effective with discharges on and after April 1, 2026, reflecting the new procedure codes. The updated software, along with the updated ICD-10 MS-DRG Version 43.1 Definitions Manual and the Definitions of Medicare Code Edits Version 43.1 manual is available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software>.

In the September 7, 2001 Medicare Program: Payments for New Medical Services and New Technologies Under the Acute Care Hospital Inpatient Prospective Payment System final rule implementing the IPPS new technology add-on payments (66 FR 46902), we indicated our intention to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of the Medicare Modernization Act (Pub. L. 108-173) included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the

amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108-173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available six months earlier than would be possible with updates occurring only once a year on October 1.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108-173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD-10 (previously ICD-9-CM) Coordination and Maintenance Committee meeting were considered for an April 1 update if a strong and convincing case was made by the requestor during the Committee’s public meeting. The request needed to identify the reason why a new code was needed in April for purposes of the new technology process. Meeting participants and those reviewing the Committee meeting materials were provided with the opportunity to comment on the expedited request. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950) for further discussion of the implementation of this prior April 1 update for purposes of the new technology add-on payment process.

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956), we adopted an April 1 implementation date, in addition to the annual October 1 update, beginning with April 1, 2022. We noted that the intent of this April 1 implementation date was to allow flexibility in the ICD-

10 code update process. CMS uses the same process for consideration of all requests for an April 1 implementation date, including for purposes of the new technology add-on payment process (that is, the prior process for consideration of an April 1 implementation date only if a strong and convincing case was made by the requestor during the meeting no longer applies). We implement new codes through the April 1 code update, which includes displaying proposals for April 1 consideration in association with the Fall ICD-10 Coordination and Maintenance Committee code update, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments consistent with the new Grouper release information. We note that under our established process, requestors indicate whether they are submitting their code request for consideration for an April 1 implementation date or an October 1 implementation date. The ICD-10 Coordination and Maintenance Committee makes reasonable efforts to accommodate the requested implementation date for each request submitted. However, the Committee ultimately determines which requests are to be presented for consideration for an April 1 implementation date or an October 1 implementation date. The ICD-10 Coordination and Maintenance Committee may not be able to consider all requests received for the next Committee code update and will determine if it would be appropriate to postpone consideration of any code requests to a future update. As discussed earlier in this section of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, there were procedure code proposals considered for an April 1, 2026 implementation for the Fall 2025 procedure code update. Following the receipt of public comments, the code proposals were approved and finalized, therefore, new codes were implemented on April 1, 2026.

Consistent with the process we outlined for the April 1 implementation date, we announced the new codes in November 2025 and provided the updated code files in December 2025. The NCHS provided the ICD-10-CM

Official Guidelines for Coding and Reporting in January 2026. On February 03, 2026, we made available the updated Version 43.1 ICD-10 MS-DRG Grouper software and related materials on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software>.

ICD-9-CM addendum and code title information are published on the CMS website at <https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum>. ICD-10-CM and ICD-10-PCS addendum and code title information are published on the CMS website at <https://www.cms.gov/Medicare/Coding/ICD10>. CMS also sends electronic files containing all ICD-10-CM and ICD-10-PCS coding changes to its Medicare contractors for use in updating their systems and furnishing education to providers. Information on ICD-10-CM diagnosis codes, along with the Official ICD-10-CM Coding Guidelines, can be found on the CDC website at <https://www.cdc.gov/nchs/icd/icd-10-cm/files.html>. Additionally, information on new, revised, and deleted ICD-10-CM diagnosis and ICD-10-PCS procedure codes is provided to the AHA for publication in the Coding Clinic for ICD-10. The AHA also distributes coding update information to publishers and software vendors.

For FY 2026, there are currently 74,719 diagnosis codes and 79,193 procedure codes. As displayed in Table 6A.—New Diagnosis Codes and in Table 6B.—New Procedure Codes associated with this FY 2027 IPPS/LTCH PPS proposed rule (and available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS>), there are 184 new diagnosis codes and 81 new procedure codes that have been finalized for FY 2027 at the time of the development of this FY 2027 IPPS/

LTCH PPS proposed rule and 80 new procedure codes that were effective with discharges on and after April 1, 2026. As noted above, the code titles are adopted as part of the ICD-10 Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

#### 16. Replaced Devices Offered Without Cost or With a Credit

##### a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS-DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS-DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS-DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

##### b. Proposed Changes for FY 2027

As discussed in section II.C.3. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, for FY 2027, under MDC 05, we are proposing to delete MS-DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with and without MCC, respectively) and

MS-DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively) and create new MS-DRGs 210 and 211 (Cardiac Pacemaker Revision or Device Replacement with and without MCC, respectively). The procedures currently assigned to MS-DRGs 258, 259, 260, 261, and 262 are being proposed for assignment to proposed new MS-DRGs 210 and 211.

Additionally, as discussed in section II.C.4. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, for FY 2027, under MDC 08, we are proposing to delete MS-DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively) and create new MS-DRG 449 (Revision of Hip or Knee Replacement). The procedures currently assigned to MS-DRGs 466, 467, and 468 are being proposed for assignment to proposed new MS-DRG 449.

As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24409), we generally map new MS-DRGs onto the list when they are formed from procedures previously assigned to MS-DRGs that are already on the list. Currently, MS-DRGs 258, 259, 260, 261, 262, 466, 467, and 468 are on the list of MS-DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit. Therefore, we are proposing that if the applicable proposed MS-DRG changes are finalized, we also would add proposed new MS-DRGs 210 and 211 and proposed new MS-DRG 449 to the list of MS-DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit as reflected in the following table. We also propose to continue to include the existing MS-DRGs currently subject to the policy as displayed in the following table.

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| MDC     | MS-DRG | MS-DRG TITLE                                                                                                                                      |
|---------|--------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Pre-MDC | 001    | Heart Transplant or Implant of Heart Assist System with MCC                                                                                       |
| Pre-MDC | 002    | Heart Transplant or Implant of Heart Assist System without MCC                                                                                    |
| 01      | 023    | Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Antineoplastic Implant or Epilepsy with Neurostimulator |
| 01      | 024    | Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC                                                         |
| 01      | 025    | Craniotomy and Endovascular Intracranial Procedures with MCC                                                                                      |
| 01      | 026    | Craniotomy and Endovascular Intracranial Procedures with CC                                                                                       |
| 01      | 027    | Craniotomy and Endovascular Intracranial Procedures without CC/MCC                                                                                |
| 01      | 040    | Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC                                                                            |
| 01      | 041    | Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator                                               |
| 01      | 042    | Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC                                                                      |
| 03      | 140    | Major Head and Neck Procedures with MCC                                                                                                           |
| 03      | 141    | Major Head and Neck Procedures with CC                                                                                                            |
| 03      | 142    | Major Head and Neck Procedures without CC/MCC                                                                                                     |
| 05      | 209    | Complex Aortic Arch Procedures                                                                                                                    |
| 05      | 210    | Cardiac Pacemaker Revision or Device Replacement with MCC                                                                                         |
| 05      | 211    | Cardiac Pacemaker Revision or Device Replacement without MCC                                                                                      |
| 05      | 213    | Endovascular Abdominal Aorta with Iliac Branch Procedures                                                                                         |
| 05      | 215    | Other Heart Assist System Implant                                                                                                                 |
| 05      | 216    | Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC                                                      |
| 05      | 217    | Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC                                                       |
| 05      | 218    | Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC                                                |
| 05      | 219    | Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC                                                   |
| 05      | 220    | Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC                                                    |
| 05      | 221    | Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC                                             |
| 05      | 242    | Permanent Cardiac Pacemaker Implant with MCC                                                                                                      |
| 05      | 243    | Permanent Cardiac Pacemaker Implant with CC                                                                                                       |
| 05      | 244    | Permanent Cardiac Pacemaker Implant without CC/MCC                                                                                                |
| 05      | 245    | AICD Generator Procedures                                                                                                                         |
| 05      | 265    | AICD Lead Procedures                                                                                                                              |
| 05      | 266    | Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC                                                                         |
| 05      | 267    | Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC                                                                      |
| 05      | 268    | Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC                                                                              |
| 05      | 269    | Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC                                                                           |
| 05      | 270    | Other Major Cardiovascular Procedures with MCC                                                                                                    |
| 05      | 271    | Other Major Cardiovascular Procedures with CC                                                                                                     |
| 05      | 272    | Other Major Cardiovascular Procedures without CC/MCC                                                                                              |
| 05      | 275    | Cardiac Defibrillator Implant with Cardiac Catheterization and MCC                                                                                |
| 05      | 276    | Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator                                                                           |
| 05      | 277    | Cardiac Defibrillator Implant without MCC                                                                                                         |
| 05      | 319    | Other Endovascular Cardiac Valve Procedures with MCC                                                                                              |
| 05      | 320    | Other Endovascular Cardiac Valve Procedures without MCC                                                                                           |
| 08      | 449    | Revision of Hip or Knee Replacement                                                                                                               |
| 08      | 461    | Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC                                                                          |
| 08      | 462    | Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC                                                                       |
| 08      | 469    | Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement                                       |
| 08      | 470    | Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC                                                               |
| 08      | 521    | Hip Replacement with Principal Diagnosis of Hip Fracture with MCC                                                                                 |
| 08      | 522    | Hip Replacement with Principal Diagnosis of Hip Fracture without MCC                                                                              |

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The final list of MS-DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be included in the FY 2027 IPPS/LTCH PPS final rule and also will be issued to

providers in the form of a Change Request (CR).

***D. Recalibration of the FY 2027 MS-DRG Relative Weights*****1. Data Sources for Developing the Relative Weights**

Consistent with our established policy, in developing the MS-DRG

relative weights for FY 2027, we are proposing to use two data sources: claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2025 MedPAR data used in this proposed rule includes discharges occurring on October 1, 2024, through September 30, 2025, based on bills received by CMS through December 31, 2025, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS).

The FY 2025 MedPAR file used in calculating the relative weights includes data for approximately 6,936,972 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR “GHO Paid” indicator field on the claim record is equal to “1” or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR “Indirect Medical Education (IME)” payment field, indicating that the claim was an “IME only” claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 2025 update of the FY 2025 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called “claim type.” Claim type “60” indicates that the claim was an inpatient claim paid as fee-for-service. Claim types “61,” “62,” “63,” and “64” relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2027 also excludes claims with claim type values not equal to “60.” The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. In addition, the data exclude Rural Emergency Hospitals (REHs), including hospitals that subsequently became REHs after the period from which the data were taken. We note that the proposed FY 2027 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2025 MedPAR claims data, grouped through the ICD–10 version of the proposed FY 2027 GROUPE (Version 44).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the Healthcare Cost

Report Information System (HCRIS). In general, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, for this proposed rule, we used the December 2025 update of the FY 2024 HCRIS for calculating the FY 2027 cost-based relative weights. Consistent with our historical practice, for this FY 2027 proposed rule, we are providing the version of the HCRIS from which we calculated these 19 cost-to-charge-ratios (CCRs) on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS>. Click on the link on the left side of the screen titled “FY 2027 IPPS Proposed Rule Home Page” or “Acute Inpatient Files for Download.”

## 2. Methodology for Calculation of the Relative Weights

### a. General

We calculated the proposed FY 2027 relative weights based on 19 CCRs. The methodology we are proposing to use to calculate the FY 2027 MS-DRG cost-based relative weights based on claims data in the FY 2025 MedPAR file and data from the FY 2024 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2027 MS–DRG classifications discussed in sections II.B. and II.C. of the preamble of this proposed rule.
- The transplant cases that were used to establish the relative weights for heart and lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2025 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis.

Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

Section 108 of the Further Consolidated Appropriations Act, 2020 provides that, for cost reporting periods beginning on or after October 1, 2020,

costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant shall be paid on a reasonable cost basis. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of the reasonable cost basis payment for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842). For FY 2022 and subsequent years, we subtract the hematopoietic stem cell acquisition charges from the total charges on each transplant bill that showed hematopoietic stem cell acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than \$30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.

- At least 92.5 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.

- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.

- Effective October 1, 2008, because hospital inpatient claims include a Present on Admission (POA) field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to “Y” for “Yes” for all claims that otherwise have an “N” (No) or a “U” (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as

indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a “Y” indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS-DRG). If the particular condition is not present on admission (that is, an “N” indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS-DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS-DRGs prior to the relative weight-setting process, the relative weights of these particular MS-DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS-DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to “Y” only for relative weight-setting purposes for all claims that otherwise have an “N” or a “U” in the POA field. This resetting “forced” the more costly HAC claims into the higher severity MS-DRGs as appropriate, and the relative weights calculated for each MS-DRG more closely reflect the true costs of those cases.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the proposed applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, proposed

cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS-DRG for each of the 19 cost groups so that each MS-DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the proposed national average CCRs developed from the FY 2024 cost report data.

The 19 cost centers that we used in the relative weight calculation are shown in a supplemental data file, Cost Center HCRIS Lines Supplemental Data File, posted via the internet on the CMS website for this proposed rule and available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS>. The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs. If we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy.

Consistent with historical practice, we account for rare situations of non-monotonicity in a base MS-DRG and its severity levels, where the mean cost in the higher severity level is less than the mean cost in the lower severity level, in determining the relative weights for the different severity levels. If there are initially non-monotonic relative weights in the same base DRG and its severity levels, then we combine the cases that group to the specific non-monotonic MS-DRGs for purposes of relative weight calculations. For example, if there are two non-monotonic MS-DRGs, combining the cases across those two MS-DRGs results in the same relative weight for both MS-DRGs. The relative weight calculated using the combined cases for those severity levels is monotonic, effectively removing any non-monotonicity with the base DRG and its severity levels. For this FY 2027 proposed rule, this calculation was applied to address non-monotonicity for cases that grouped to the following: MS-DRG 217 and MS-DRG 218, MS-DRG 504 and MS-DRG 505, and MS-DRG 582 and 584. In the supplemental file titled AOR/BOR File, we include statistics for the affected MS-DRGs both separately and with cases combined.

We are inviting public comments on our proposals related to recalibration of the proposed FY 2027 relative weights and the changes in relative weights from FY 2026.

#### b. Relative Weight Calculation for MS-DRG 018

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58451 through 58453), we created MS-DRG 018 for cases that include procedures describing CAR T-cell therapies. We also finalized our proposal to modify our existing relative weight methodology to ensure that the relative weight for MS-DRG 018 appropriately reflects the relative resources required for providing CAR T-cell therapy outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS-DRGs (85 FR 58599 through 58600). Specifically, we stated that clinical trial claims that group to new MS-DRG 018 would not be included when calculating the average cost for MS-DRG 018 that is used to calculate the relative weight for this MS-DRG, so that the relative weight reflects the costs of the CAR T-cell therapy drug. We stated that we identified clinical trial claims as claims that contain ICD-10-CM diagnosis code Z00.6 or contain standardized drug charges of less than \$373,000, which was the average sales price of KYMRIA and YESCARTA, the two CAR T-cell biological products licensed to treat relapsed/refractory large B-cell lymphoma as of the time of the development of the FY 2021 final rule. In addition, we stated that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for new MS-DRG 018 to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for new MS-DRG 018 to the extent such cases can be identified in the historical data.

We also finalized our proposal to calculate an adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS-DRGs and for purposes of budget neutrality and outlier simulations. We calculate this adjustor by dividing the average cost for cases that we identify as clinical trial cases by the average cost for cases that we identify as non-clinical trial cases, with the additional refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be

clinical trial cases to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases to the extent such cases can be identified in the historical data. We stated that to the best of our knowledge, there were no claims in the historical data used in the calculation of this adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than \$373,000.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58842), we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access use immunotherapy cases that group to MS-DRG 018, and indicated that we would provide instructions for identifying these claims in separate guidance. Following the issuance of the FY 2021 IPPS/LTCH PPS final rule, we issued guidance<sup>16</sup> stating that providers may enter a Billing Note NTE02 “Expand Acc Use” on the electronic claim 837I or a remark “Expand Acc Use” on a paper claim to notify the MAC of expanded access use of CAR T-cell therapy. In this case, the MAC would add payer-only condition code “ZB” so that Pricer will apply the payment adjustment in calculating payment for the case. In cases when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the provider may enter a Billing Note NTE02 “Diff Prod Clin Trial” on the electronic claim 837I or a remark “Diff Prod Clin Trial” on a paper claim. In this case, the MAC would add payer-only condition code “ZC” so that the Pricer will not apply the payment adjustment in calculating payment for the case.

In the FY 2022 IPPS/LTCH PPS final rule, we revised MS-DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 44806). We also finalized our proposal to continue to use the proxy of standardized drug charges of less than \$373,000 (86 FR 44965) to identify clinical trial claims. We also finalized use of this same proxy for the FY 2023 IPPS/LTCH PPS final rule (87 FR 48894).

Following the issuance of the FY 2023 IPPS/LTCH PPS final rule, we issued guidance<sup>17</sup> stating where there is expanded access use of immunotherapy, the provider may submit condition code “90” on the claim so that Pricer will apply the payment adjustment in calculating payment for the case. We stated that MACs would no longer append Condition Code ‘ZB’ to inpatient claims reporting Billing Note NTE02 “Expand Acc Use” on the electronic claim 837I or a remark “Expand Acc Use” on a paper claim, effective for claims for discharges that occur on or after October 1, 2022.

In the FY 2024 IPPS/LTCH PPS final rule, we explained that the MedPAR claims data now includes a field that identifies whether or not the claim includes expanded access use of immunotherapy. We stated that for the FY 2022 MedPAR claims data, this field identifies whether or not the claim includes condition code ZB, and for the FY 2023 MedPAR data and subsequent years, this field will identify whether or not the claim includes condition code 90. We further noted that the MedPAR files now also include a variable that indicates whether the claim includes the payer-only condition code “ZC”, which identifies a case involving the clinical trial of a different product where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner.

Accordingly, and as discussed further in the FY 2024 IPPS/LTCH PPS final rule, we finalized two modifications to our methodology for identifying clinical trial claims and expanded access use claims in MS-DRG 018 (88 FR 58791). First, we finalized to exclude claims with the presence of condition code “90” (or, for FY 2024 ratesetting, which was based on the FY 2022 MedPAR data, the presence of condition code “ZB”) and claims that contain ICD-10-CM diagnosis code Z00.6 without payer-only code “ZC” that group to MS-DRG 018 when calculating the average cost for MS-DRG 018. Second, we finalized to no longer use the proxy of standardized drug charges of less than \$373,000 to identify clinical trial claims and expanded access use cases when calculating the average cost for MS-DRG 018. Accordingly, we finalized that in calculating the relative weight for MS-DRG 018 for FY 2024, only those claims that group to MS-DRG 018 that (1) contain ICD-10-CM diagnosis code Z00.6 and do not include payer-only code “ZC” or (2) contain condition code “ZB” (or, for subsequent fiscal years,

condition code “90”) would be excluded from the calculation of the average cost for MS-DRG 018. Consistent with this, we also finalized modifications to our calculation of the adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS-DRGs. We refer readers to the FY 2024 IPPS/LTCH PPS final rule for further discussion of these modifications (88 FR 58791).

Consistent with the FY 2026 IPPS/LTCH PPS final rule, in this proposed rule, for FY 2027 we are proposing to continue to use our methodology as modified in the FY 2024 IPPS/LTCH PPS final rule for identifying clinical trial claims and expanded access use claims in MS-DRG 018, with an additional modification as discussed in this section. First, we exclude claims with the presence of condition code “90” and claims that contain ICD-10-CM diagnosis code Z00.6 without payer-only code “ZC” that group to MS-DRG 018 when calculating the average cost for MS-DRG 018. Second, we no longer use the proxy of standardized drug charges of less than \$373,000 to identify clinical trial claims and expanded access use cases when calculating the average cost for MS-DRG 018.

In the FY 2026 IPPS/LTCH PPS final rule, we finalized our proposal to apply the payment adjustment for clinical trial and expanded access use immunotherapy cases to other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost. To mirror this change within our relative weight methodology, we finalized our proposal to also exclude claims with standardized drug charges below the median standardized drug charge of claims identified as clinical trials in MS-DRG 018 when we calculate the average cost for MS-DRG 018. We proposed to apply this policy for 2 years (that is, in our relative weight methodology for MS-DRG 018 for FYs 2026 and 2027), until the claims data reflects the addition of the condition code indicating that the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, which then would be able to be used to identify these cases such that they can be identified for exclusion from the calculation of the average cost of MS-DRG 018. For this proposed rule, based on the December 2025 update of the FY 2025 MedPAR file, we estimated that the median standardized drug charge of claims identified as clinical trials in MS-DRG 018 is \$25,323. For the

<sup>16</sup> <https://www.cms.gov/files/document/r10571cp.pdf>.

<sup>17</sup> <https://www.cms.gov/files/document/r11727cp.pdf>.

purpose of performing this trim, we propose to update the median standardized drug charge of claims identified as clinical trials in MS-DRG 018 based on more recent data for the final rule.

Accordingly, we are proposing that in calculating the relative weight for MS-DRG 018 for FY 2027, in identifying clinical trial claims and expanded access use claims and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, only those claims that group to MS-DRG 018 that (1) contain ICD-10-CM diagnosis code Z00.6 and do not include payer-only code “ZC”, (2) contain condition code “90”, or (3) contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS-DRG 018 would be excluded from the calculation of the average cost for MS-DRG 018.

We are also proposing to continue to use the methodology as modified in the FY 2024 IPPS/LTCH PPS final rule to calculate the adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS-DRGs, with the same proposed modification as described previously to identify other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost:

- Calculate the average cost for cases assigned to MS-DRG 018 that (a) contain ICD-10-CM diagnosis code Z00.6 and do not contain condition code “ZC”, (b) contain condition code “90”, or (c) contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS-DRG 018.

- Calculate the average cost for all other cases assigned to MS-DRG 018.

- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.

- Apply the adjustor calculated in step 3 to the cases identified in step 1 as applicable clinical trial or expanded access use cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS-DRGs.

Under our proposal to continue to apply this methodology, with the proposed modification as described, based on the December 2025 update of the FY 2025 MedPAR file used for this proposed rule, we estimate that the average costs of cases assigned to MS-

DRG 018 that are identified as clinical trial cases (\$71,039) were 17 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases (\$412,218). Accordingly, as we did for FY 2026, we are proposing to adjust the transfer-adjusted case count for MS-DRG 018 by applying the proposed adjustor of 0.17 to the applicable clinical trial and expanded access use immunotherapy cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, and to use this adjusted case count for MS-DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of this proposed rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, was adjusted by 0.17. As we did for FY 2026, we are applying the same adjustor for the applicable cases that group to MS-DRG 018 for purposes of budget neutrality and outlier simulations. We are also proposing to update the value of the adjustor based on more recent data for the final rule.

#### c. Cap for Relative Weight Reductions

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a permanent 10-percent cap on the reduction in an MS-DRG's relative weight in a given fiscal year, beginning in FY 2023. We also finalized a budget neutrality adjustment to the standardized amount for all hospitals to ensure that application of the permanent 10-percent cap does not result in an increase or decrease of estimated aggregate payments. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion of this policy. In the Addendum to this IPPS/LTCH PPS proposed rule, we present the proposed budget neutrality adjustment for reclassification and recalibration of the FY 2027 MS-DRG relative weights with application of this cap. We are also making available on the CMS website a supplemental file demonstrating the application of the permanent 10 percent cap for FY 2027. For a further discussion of the final budget neutrality adjustment for FY 2027, we refer readers to the Addendum of this proposed rule.

#### 3. Development of National Average Cost-to-Charge Ratios (CCRs)

We developed the proposed national average CCRs as follows:

Using the FY 2024 cost report data, we removed CAHs, REHs, Indian Health Service hospitals, all inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D-3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D-3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS-DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 “costs” across each MS-DRG to produce a total standardized cost for the MS-DRG. The average standardized cost for each MS-DRG was then computed as the total standardized cost for the MS-DRG divided by the transfer-adjusted case count for the MS-DRG. The average cost for each MS-DRG was then divided by the national average standardized cost per case to determine the relative weight. The proposed FY 2027 cost-based relative weights were then normalized by an adjustment factor of 1.944557 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act. We then applied the permanent 10-percent cap on the reduction in a MS-DRG's relative weight in a given

fiscal year; specifically for those MS-DRGs for which the relative weight otherwise would have declined by more than 10 percent from the FY 2026 relative weight, we set the proposed FY 2027 relative weight equal to 90 percent

of the FY 2026 relative weight. The proposed relative weights for FY 2027 as set forth in Table 5 associated with this proposed rule and available on the CMS website at [https://www.cms.gov/](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-)

*Payment/AcuteInpatientPPS* reflect the application of this cap.

The 19 proposed national average CCRs for FY 2027 are as follows:

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| NATIONAL AVERAGE CCRS        |       |
|------------------------------|-------|
| Group                        | CCR   |
| Routine Days                 | 0.377 |
| Intensive Days               | 0.324 |
| Drugs and Cellular Therapies | 0.18  |
| Supplies & Equipment         | 0.301 |
| Implantable Devices          | 0.256 |
| Inhalation Therapy           | 0.141 |
| Therapy Services             | 0.258 |
| Anesthesia                   | 0.074 |
| Labor & Delivery             | 0.37  |
| Operating Room               | 0.151 |
| Cardiology                   | 0.086 |
| Cardiac Catheterization      | 0.07  |
| Laboratory                   | 0.095 |
| Radiology                    | 0.122 |
| MRIs                         | 0.065 |
| CT Scans                     | 0.032 |
| Emergency Room               | 0.133 |
| Blood and Blood Products     | 0.238 |
| Other Services               | 0.323 |

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS-DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We are proposing to

use that same case threshold in recalibrating the proposed MS-DRG relative weights for FY 2027. Using data from the FY 2025 MedPAR file, there are 8 MSDRGs that contain fewer than 10 cases. For FY 2027, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights

for these low-volume MS-DRGs, we are proposing to compute relative weights for the low volume MS-DRGs by adjusting their final FY 2026 relative weights by the percentage change in the average weight of the cases in other MS-DRGs from FY 2026 to FY 2027. The crosswalk table is as follows.

| LOW-VOLUME MS-DRGS |                                                              |                                                                                                            |
|--------------------|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| Low-Volume MS-DRG  | MS-DRG Title                                                 | Crosswalk to MS-DRG                                                                                        |
| 789                | Neonates, Died or Transferred to Another Acute Care Facility | Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 790                | Extreme Immaturity or Respiratory Distress Syndrome, Neonate | Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 791                | Prematurity with Major Problems                              | Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 792                | Prematurity without Major Problems                           | Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 793                | Full-Term Neonate with Major Problems                        | Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 794                | Neonate with Other Significant Problems                      | Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 795                | Normal Newborn                                               | Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |
| 796                | Vaginal Delivery with Sterilization and/or D&C with MCC      | Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs) |

## BILLING CODE 4120-01-C

*E. Add-On Payments for New Services and Technologies for FY 2027*

## 1. Background

Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies (sometimes collectively referred to in this section as “new technologies”) under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. The regulations at 42 CFR 412.87 implement these provisions and § 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d).

We note that section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act. Therefore, as discussed in prior rulemaking (72 FR 47307 through 47308), we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs.

In this proposed rule, we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For further discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

## a. New Technology Add-on Payment Criteria

## (1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will no longer be considered “new” for purposes of new medical service or technology add-on payments after CMS has recalibrated the MS-DRGs, based on available data, to reflect the cost of the technology. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA marketing authorization, it may not necessarily be considered “new” for purposes of new technology add-on payments if it is “substantially similar” to another medical product that was market authorized by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically whether: (1) a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) a product is assigned to the same or a different MS-DRG; and (3) the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered “new” for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

## (2) Cost Criterion

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for

new medical services or technologies, the MS-DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS-DRG prospective payment rate, we evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS-DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS-DRGs if the new medical service or technology occurs in many different MS-DRGs). The MS-DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2027 are presented in a data file that is available, along with the other data files associated with the FY 2026 IPPS/LTCH PPS final rule on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index>.

We note that, under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58603 through 58605), beginning with FY 2022, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS-DRG for that same fiscal year.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the proposed thresholds for applications for new technology add-on payments for FY 2028 are presented in a data file that is available on the CMS website, along with the other data files associated with this FY 2027 proposed rule, by clicking on the FY 2027 IPPS Proposed Rule Home Page at: <https://www.cms.gov/Medicare/>



*Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.*

In the September 7, 2001, final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. We also discussed in the September 7, 2001, final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule at 45 CFR part 160 and subparts A and E of 45 CFR part 164, applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for further information on this issue.

**(3) Substantial Clinical Improvement Criterion**

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292), we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or

offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

- Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

- The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

- The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292) for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS final rule (67 FR 50015), that while FDA has regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not rely upon FDA criteria in our evaluation of substantial clinical improvement for purposes of determining what services and technologies qualify for new technology add-on payments under Medicare. This criterion does not depend on the standard of safety and effectiveness on which FDA relies but on a demonstration of substantial clinical improvement in the Medicare population.

**b. Alternative Inpatient New Technology Add-On Payment Pathway**

Beginning with applications for FY 2021 new technology add-on payments, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program may qualify for the new technology add-on payment under an alternative pathway. Additionally, under the regulations at § 412.87(d) for certain antimicrobial products, beginning with FY 2021, a drug that is designated by FDA as a Qualified Infectious Disease Product (QIDP), and, beginning with FY 2022, a drug that is approved by FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), may also qualify for the new technology add-on payment under an alternative pathway. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy. We note that CMS reviews the application based on the information provided by the applicant only under the alternative pathway specified by the applicant at the time of application submission. To receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable. We note, in section II.E.7. of this proposed rule, we are proposing to repeal the alternative pathway for new technology add-on payment beginning with applications received for new technology add-on payments for FY



2028 and require all applicants for new technology add-on payments to demonstrate that they meet all eligibility requirements to receive add-on payments. (We refer the reader to section II.E.7. of this proposed rule for a complete discussion regarding this proposal.)

#### (1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, a medical device designated under FDA's Breakthrough Devices Program<sup>18</sup> that has received FDA marketing authorization will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway, a medical device that has received a Breakthrough Device designation, and then received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) for the indication covered by the Breakthrough Device designation, will need to meet the requirements of § 412.87(c). We note that in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736), we clarified our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736) for further discussion regarding this clarification.

#### (2) Alternative Pathway for Certain Antimicrobial Products

For applications received for new technology add-on payments for certain antimicrobial products, beginning with FY 2021, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, and, beginning with FY 2022, if a drug is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway, it will be considered not substantially similar to an existing technology for purposes of new technology add-on payments and will

not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway for QIDPs and LPADs, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP or approved under the LPAD pathway will need to meet the requirements of § 412.87(d). We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy.

We note that, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739), we clarified that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive FDA marketing authorization for the indication covered by the QIDP designation. We also finalized our policy to expand our alternative new technology add-on payment pathway for certain antimicrobial products to include products approved under the LPAD pathway and used for the indication approved under the LPAD pathway.

#### c. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. As noted previously, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (72 FR 47307 through 47308).

For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying operating cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), CMS made an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product approved under FDA's LPAD pathway, beginning with discharges on or after October 1, 2020, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS-DRG payment plus 65 percent (or 75 percent for certain antimicrobial products (QIDPs and LPADs)) of the estimated costs of the new technology or medical service. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300) for further discussion on the increase in the new technology add-on payment beginning with discharges on or after October 1, 2019.

<sup>18</sup> Breakthrough Devices Program <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>.

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69245 through 69252), we finalized an increase in the new technology add-on payment percentage, reflected at § 412.88(a)(2)(ii)(C) and (b)(2)(iv), that for certain gene therapies approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule that are indicated and used specifically for the treatment of sickle cell disease (SCD), effective with discharges on or after October 1, 2024 and concluding at the end of the 2- to 3-year newness period for such therapy, if the costs of a discharge (determined by applying CCRs as described in § 412.84(h)) involving the use of such therapy for the treatment of SCD exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. We noted that these payment amounts would only apply to Casgevy™ (exagamglogene autotemcel) and Lyfgenia™ (lovotibeglogene autotemcel), when indicated and used specifically for the treatment of SCD, which were approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69128 through 69135, and 89 FR 69188 through 69196).

We note that, consistent with the prospective nature of the IPPS, we finalize the new technology add-on payment amount for technologies approved or conditionally approved for new technology add-on payments in the final rule for each fiscal year and do not make mid-year changes to new technology add-on payment amounts. Updated cost information may be submitted and included in rulemaking to be considered for the following fiscal year.

Section 503(d)(2) of the MMA (Pub. L. 108–173) provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of the MMA, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

#### d. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulation at § 412.87 to codify our

longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We specified that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to the regulation to indicate that new technologies must receive FDA marketing authorization<sup>19 20</sup> (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; or approval of a New Drug Application (NDA) or Biologics License Application (BLA)) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered (85 FR 58742). Consistent with our longstanding policy, we consider FDA marketing authorization as representing that a product has received FDA approval or clearance, or has been granted a De Novo classification request when considering eligibility for the new technology add-on payment.

Additionally, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58739 through 58742), we finalized our proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments, provided that the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-

on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments. As noted, in section II.E.7. of this proposed rule, we are proposing to repeal the alternative pathway for new technology add-on payment, such that beginning with applications received for new technology add-on payments for FY 2028, in order to be eligible for consideration for the new technology add-on payment for the upcoming fiscal year, all applicants would need to receive FDA marketing authorization by May 1 prior to the particular fiscal year for which the application is being considered.

As discussed in the FY 2024 and FY 2025 IPPS/LTCH PPS final rules (88 FR 58948 through 58958 and 89 FR 69242 through 69245, respectively), beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance (for a 510(k) or De Novo Classification request submission) or filing (for a PMA, NDA, or BLA) to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958) and the FY 2025 IPPS/LTCH PPS final rule (89 FR 69242 through 69245). As we have discussed in prior rulemaking, we consider the application to be complete when the full application has been submitted to FDA and FDA has provided documentation to the applicant indicating that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA. We further stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36661 through 36662) that we recognize that FDA processes and documentation may change over time, and the acceptance or filing documentation may vary depending on the type of FDA marketing authorization application the applicant has submitted to FDA. For example, we understand that FDA considers submission of a 510(k) or De Novo Classification request

<sup>19</sup> How to Study and Market Your Device <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device>.

<sup>20</sup> Types of Applications <https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/types-applications>.

to be accepted for substantive review after the completion of either a refuse to accept (RTA) review or a technical screening process.<sup>21 22</sup> Submissions of 510(k) and De Novo Classification requests undergo a technical screening process when they are submitted to FDA using the electronic Submission Template And Resource (eSTAR) process; 510(k) and De Novo Classification requests that are not submitted via eSTAR undergo an RTA review. Accordingly, FDA provides applicants using eSTAR with a review assignment notification to indicate that FDA has completed its technical screening process and has determined that the submission is sufficiently complete to allow for substantive review. Therefore, new technology add-on payment applicants that have submitted a 510(k) or De Novo Classification request submission to FDA through eSTAR must submit a copy of the review assignment notification to CMS (at the time of new technology add-on payment application) to establish the application is sufficiently complete to allow for substantive review by FDA. We noted that PMAs submitted using eSTAR that complete technical screening will still undergo a subsequent filing review by FDA, after which an application is determined to be sufficiently complete to allow for substantive review; therefore, we continue to require documentation of FDA filing for these applications. We also stated that we recognize that FDA does not conduct a new filing review for NDA or BLA applications that were the subject of a Complete Response Letter (CRL) and were subsequently resubmitted to FDA, even though resubmissions are considered a new review cycle.<sup>23 24</sup> Therefore, beginning with the new technology add-on applications submitted for FY 2027, these new technology add-on payment applicants must provide to CMS a copy of the

resubmission acknowledgement letter from FDA that provides the new goal date for FDA review of the application. We further note that if there are other processes not described here, or if there are further changes to FDA's review processes, consistent with our policy, applicants must provide to CMS the most up-to-date documentation that indicates FDA has determined that the application is sufficiently complete to allow for substantive review by FDA.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958), we also finalized that, beginning with FY 2025 applications, in order to be eligible for consideration for the new technology add-on payment for the upcoming fiscal year, an applicant for new technology add-on payments must have received FDA marketing authorization by May 1 (rather than July 1) of the year prior to the beginning of the fiscal year for which the application is being considered (except for an application that is submitted under the alternative pathway for certain antimicrobial products), as reflected at § 412.87(f)(2) and (3), as amended and redesignated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958, 88 FR 59331). As noted, in section II.E.7. of this proposed rule, we are proposing to repeal the alternative pathway for new technology add-on payment, such that beginning with the FY 2028 new technology add-on payment applications, in order to be eligible for consideration for the new technology add on payment for the upcoming fiscal year, all applicants would need to receive FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

#### e. Pharmaceutical & Technology Ombudsman (PTO)

Many interested parties (including device/biologic/drug developers or manufacturers, industry consultants, others) engage with CMS for coverage, coding, and payment questions or concerns. In order to streamline engagement by centralizing the different innovation pathways within CMS including new technology add-on payments, CMS utilizes the Pharmaceutical & Technology Ombudsman as an initial resource for interested parties. This Ombudsman is available to assist with all of the following:

- Help to point interested parties to or provide information and resources where possible regarding process, requirements, and timelines.
- As necessary, coordinate and facilitate opportunities for interested

parties to engage with various CMS components.

- Serve as a primary point of contact for interested parties and provide updates on developments where possible or appropriate.

We receive many questions from parties interested in pursuing new technology add-on payments who may not be entirely familiar with working with CMS. While we encourage interested parties to first review our resources available at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies>, we know that there may be additional questions about the application process. Interested parties with further questions regarding Medicare's coverage, coding, and payment processes, and how they can navigate these processes, whether for new technology add-on payments or otherwise, should review the updated resource guide available at: <https://www.cms.gov/medicare/coding-billing/guide-medical-technology-companies-other-interested-parties>. Parties that would like to further discuss questions or concerns with CMS should contact the Pharmaceutical & Technology Ombudsman at [PharmTechOmbud@cms.hhs.gov](mailto:PharmTechOmbud@cms.hhs.gov).

#### f. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2028 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways as previously described, if the proposal in section II.E.7. of this proposed rule to repeal the alternative pathway for new technology add-on payment beginning with FY 2028 new technology add-on payment applications is not finalized), along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. If the proposal in section II.E.7. of this proposed rule to repeal the alternative pathway is not finalized, CMS will continue to review applications under the pathway specified by the applicant at the time of application submission. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies>.

<sup>21</sup> FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals Guidance for Industry and Food and Drug Administration Staff Document issued on October 3, 2022. <https://www.fda.gov/media/73507/download>.

<sup>22</sup> FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals Guidance for Industry and Food and Drug Administration Staff Document issued on October 3, 2022. <https://www.fda.gov/media/107652/download>.

<sup>23</sup> SOPP 8405.1: Procedures for Resubmissions to an Application or Supplement. Version: 8, Effective Date: November 13, 2022. <https://www.fda.gov/media/84417/download>.

<sup>24</sup> 21 CFR 314.110, Complete response letter to the applicant <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-314/subpart-D/section-314.110>.

[www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies](https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies).

To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2028, once the application deadline has closed, CMS will post on its website a list of the applications submitted, along with a brief description of each technology as provided by the applicant.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990), we finalized our proposal to publicly post online new technology add-on payment applications, including the completed application forms, certain related materials, and any additional updated application information submitted subsequent to the initial application submission (except certain volume, cost and other information identified by the applicant as confidential), beginning with the application cycle for FY 2024, at the time the proposed rule is published. We also finalized that with the exception of information included in a confidential information section of the application, cost and volume information, and materials identified by the applicant as copyrighted or not otherwise releasable to the public, the contents of the application and related materials may be posted publicly, and that we will not post applications that are withdrawn prior to publication of the proposed rule. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990) for further information regarding this policy. In addition, as discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36663 through 36664), beginning with the new technology add-on payment applications submitted for FY 2027, the public posting includes the applicant's explanation of the cost analysis methodology, including the step-by-step explanation of the columns used in the cost analysis spreadsheet attachment, any optional comments provided by the applicant, and information about the case weighted threshold and final inflated case weighted standardized charge per case, as is currently subject to discussion in the cost criterion analysis for each eligible application in the proposed rule. The cost analysis spreadsheet attachment and other cost or charge values that may have been provided in the applicant's responses in the cost criterion section are not included in the public posting. Certain cost and volume information may still be summarized

and discussed in the proposed rule, but we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the cost criterion.

We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA and approved under OMB control number 0938-1347 and has an expiration date of December 31, 2026.

## 2. Public Input Before Publication of a Notice of Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of the MMA, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement. The process for evaluating new medical service and technology applications requires the Secretary to do all of the following:

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries.
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending.
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement.
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2027 prior to publication of the FY 2027 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on September 10, 2025 (90 FR 43613), and held a virtual town hall meeting on December 10, 2025. In the

announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2027 new medical service and technology add-on payment applications before the publication of the FY 2027 IPPS/LTCH PPS proposed rule.

Approximately 190 individuals attended the virtual town hall meeting. We posted the recordings of the virtual town hall on the CMS web page at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies>.

We considered each applicant's presentation made at the town hall meeting, as well as written comments received by the December 15, 2025 deadline, in our evaluation of the new technology add-on payment applications for FY 2027 in the development of the FY 2027 IPPS/LTCH PPS proposed rule. In response to the published notice and the New Technology Town Hall meeting, we received written comments regarding the applications for FY 2027 new technology add-on payments. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (90 FR 43613), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion with regard to pending new technology add-on payment applications for FY 2027. Therefore, we are not summarizing any written comments in this proposed rule that are unrelated to the substantial clinical improvement criterion. In section II.E.5. of the preamble of this proposed rule, we summarize comments regarding individual applications, or, if applicable, indicate that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

## 3. ICD-10-PCS Section "X" Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD-10-PCS includes a new section containing the new Section "X" codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD-10-PCS Section "X" codes will be handled in the same manner as the decisions for all of the other ICD-10-PCS code

changes. That is, proposals to create, delete, or revise Section “X” codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section “X” code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: <https://www.cms.gov/medicare/coding-billing/icd-10-codes>, including guidelines for ICD–10–PCS Section “X” codes. We encourage providers to view the material provided on ICD–10–PCS Section “X” codes.

#### 4. Proposed FY 2027 Status of Technologies Receiving New Technology Add-On Payments for FY 2026

In this section of the proposed rule, we discuss the proposed FY 2027 status of the 54 new technology add-on payments approved for FY 2026, as set forth in the tables that follow. Specifically, we present our proposals to continue the new technology add-on payments for FY 2027 for those technologies that were approved for the new technology add-on payment for FY 2026, and which would still be considered “new” for purposes of new technology add-on payments for FY 2027. We also present our proposals to discontinue new technology add-on payments for FY 2027 for those technologies that were approved for the new technology add-on payment for FY 2026, and which would no longer be considered “new” for purposes of new technology add-on payments for FY 2027.

Our policy is that a medical service or technology may continue to be considered “new” for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and, for technologies that were first approved for new technology add-on payments prior to FY 2025, we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year, and, in general, we have extended new technology add-on payments for these technologies for an additional year only if the 3-year anniversary date of the product’s entry

onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69238 through 69242), we finalized that, beginning with new technology add-on payments for FY 2026, in assessing whether to continue the new technology add-on payments for those technologies that are first approved for new technology add-on payments in FY 2025 or a subsequent year, we will extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of the product’s entry onto the U.S. market occurs on or after October 1 of that fiscal year. This change is effective beginning with those technologies that are initially approved for new technology add-on payments in FY 2025 or a subsequent year. For technologies that were first approved for new technology add-on payments prior to FY 2025, including for technologies we determine to be substantially similar to those technologies, we continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether a technology would still be considered “new” for purposes of new technology add-on payments.

Table II.E–01 lists the technologies that were first approved for new technology add-on payments in FY 2025 or a subsequent year, for which we are proposing to continue making new technology add-on payments for FY 2027 because they are still considered “new” for purposes of new technology add-on payments because the 3-year anniversary date of the product’s entry onto the U.S. market occurs on or after October 1, 2026. This table also presents the newness start date, new technology add-on payment start date, 3-year anniversary date of the product’s entry onto the U.S. market, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments for each technology. We refer readers to the cited final rules in the table for a complete discussion of the new technology add-on payment application, coding, and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We note that we conditionally approved CONTEPO™ (fosfomycin) for FY 2026 new technology add-on payments under the alternative pathway for certain antimicrobial products (90 FR 36831 through 36833), subject to the technology receiving FDA marketing authorization by July 1, 2026. CONTEPO™ received FDA marketing authorization on October 22, 2025, and was eligible to receive new technology

add-on payments in FY 2026 beginning with discharges on or after January 1, 2026. As CONTEPO™ received FDA marketing authorization prior to July 1, 2026, and was approved for new technology add-on payments in FY 2026, we are proposing to continue making new technology add-on payments for CONTEPO™ for FY 2027.

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36666 through 36671), in response to comments from the applicant for ZEVTERA® requesting that CMS consider the beginning of the newness period for ZEVTERA® to commence on May 20, 2025, which it stated was the date on which ZEVTERA® became commercially available on the U.S. market, we noted that that date occurred after new technology add-on payments for ZEVTERA® began, as it was approved for new technology add-on payment for FY 2025 (starting October 1, 2024). While we agreed that per our policy, we may consider a documented delay in a technology’s market availability in our determination of newness, we noted that the new technology add-on payment for claims reporting ICD–10–PCS procedure codes for ZEVTERA® (XW0335A (Introduction of ceftobiprole medocartil anti-infective into peripheral vein, percutaneous approach) and XW0435A (Introduction of ceftobiprole medocartil anti-infective into central vein, percutaneous approach)) was available beginning October 1, 2024.

Furthermore, we noted that beginning with new technology add-on payments for FY 2026, in assessing whether to continue the new technology add-on payments for those technologies that are first approved for new technology add-on payments in FY 2025 or a subsequent year, we will extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of the product’s entry onto the U.S. market occurs on or after October 1 of that fiscal year. We stated that if we were to consider the beginning of the newness period to commence on May 20, 2025, the date on which the applicant states ZEVTERA® became commercially available on the U.S. market, under our policy, the technology would potentially be eligible for new technology add-on payment for up to four years. Although the applicant stated that CMS had delayed the newness start dates for other technologies when market availability was significantly later than the FDA approval date, and that like these other products, ZEVTERA®’s newness period should commence on the date on which the technology became commercially

available, we noted that, unlike these other technologies, the applicant for ZEVTERA® was asserting a date of commercial availability that occurred after its new technology add-on payment began.

We also noted that applicants may assert a delay in commercial availability due to business decisions made by the applicant. We were concerned that a delay in commercial availability extending beyond the implementation date for the new technology add-on payment would potentially allow applicants to postpone commercial availability for an indefinite period of time while the technology (and other technologies reported using the same codes) remains eligible for new technology add-on payment.

Therefore, we questioned whether, where the applicant asserts a date of commercial availability that occurred after the new technology add-on payment for the technology began, it would be appropriate to instead consider the beginning of the newness period to commence with the start of the technology's new technology add-on payment. We noted that regardless of whether we considered the beginning of the newness period to commence for ZEVTERA® on May 20, 2025, April 3, 2024, or a date in between, the three-year anniversary date would occur after April 1, 2026, and, therefore, the technology was considered new for FY 2026.

After further review, we believe that it would be most appropriate to no longer consider commercial delays once a technology's new technology add-on payment becomes effective. We have discussed in prior rulemaking (89 FR

36136) that, generally, we use the FDA marketing authorization date as the indicator of the time when a technology begins to become available on the market and data reflecting the costs of the technology begin to become available for recalibration of the DRG weights. In specific circumstances, we have recognized a date later than the FDA marketing authorization date as the appropriate starting point for the 2- to 3-year newness period. For example, we have recognized a later date where an applicant could prove a delay in actual availability of a product after FDA approval or clearance. However, due to the increasing volume and complexity of circumstances in which applicants assert a delay in commercial availability, we believe that a delay that extends to after implementation of a new technology add-on payment should no longer be considered. For example, as discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36667), we are concerned that a delay in commercial availability extending beyond the implementation date for the new technology add-on payment would potentially allow applicants to postpone commercial availability for an indefinite period of time while the technology (and other technologies reported using the same codes) remain eligible for new technology add-on payment. We have also noted that applicants may be asserting a delay in commercial availability due to business decisions made by the applicant. In addition, because we now extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of a product's entry onto the U.S. market occurs on or after October 1 of that fiscal

year (89 FR 69238 through 69242), commercial delays as asserted by manufacturers that extend to after the new technology add-on payment becomes effective could now have a bigger impact, as they could lead to new technology add-on payments being effective for four or more years under our current policy.

Therefore, while we have considered no longer recognizing a date later than the FDA marketing authorization date as the appropriate starting point for the 2- to 3-year newness period, we are proposing that we may consider a documented delay in the beginning of a technology's newness period due to commercial availability only until the new technology add-on payment becomes effective for the fiscal year for which the applicant applied for new technology add-on payments. Under this proposal, for a technology that is not yet available for sale when its new technology add-on payment becomes effective, we would consider the newness period to begin on September 30 preceding the start of the new technology add-on payment for the technology.

As such, consistent with this proposal, because the new technology add-on payment for ZEVTERA® became effective on October 1, 2024, we consider the beginning of the newness period for ZEVTERA® to commence on September 30, 2024.

We are inviting public comments on our proposals to continue new technology add-on payments for FY 2027 for the technologies listed in Tables II.E.–01 of this proposed rule.

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**TABLE II.E.-01: PROPOSED CONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2026 NEW TECHNOLOGY ADD-ON PAYMENTS STILL CONSIDERED NEW FOR FY 2027 BECAUSE THE 3-YEAR ANNIVERSARY DATE WILL OCCUR ON OR AFTER OCTOBER 1, 2026**

|    | Technology                                                            | Newness Start Date | NTAP Start Date | 3-year Anniversary Date of Entry onto U.S. Market | Previous Final Rule Citations                          | Proposed Maximum NTAP Amount for FY 2027 | Coding Used to Identify Cases Eligible for NTAP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----|-----------------------------------------------------------------------|--------------------|-----------------|---------------------------------------------------|--------------------------------------------------------|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Amalase Enterprise CTB Triage—OH                                      | 10/10/2023         | 10/01/2024      | 10/10/2026                                        | 89 FR 69205 through 69208<br>90 FR 36665 through 36669 | \$241.39                                 | XXE0X1A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 2  | ASTur® System                                                         | 04/26/2024         | 10/01/2024      | 04/26/2027                                        | 89 FR 69208 through 69210<br>90 FR 36665 through 36669 | \$97.50                                  | XXF5X2A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 3  | Edwards EVOQUE™ Tricuspid Valve Replacement System ("EVOQUE™ System") | 02/01/2024         | 10/01/2024      | 02/01/2027                                        | 89 FR 69210 through 69213<br>90 FR 36665 through 36669 | \$31,850.00                              | X2R13RA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 4  | GORe® EXCLUDER® Thoracoabdominal Branch Endoprostheses (TAMBE Device) | 01/12/2024         | 10/01/2024      | 01/12/2027                                        | 89 FR 69213 through 69215<br>90 FR 36665 through 36669 | \$47,238.75                              | X2VTC3A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 5  | LimFlow™ System                                                       | 11/01/2023         | 10/01/2024      | 11/01/2026                                        | 89 FR 69215 through 69218<br>90 FR 36665 through 36669 | \$16,250.00                              | 041M3JS, 041N3JS, 041P3JS, 041Q3JS, 041R3JS, 041S3JS, 041T3JS, or 041U3JS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 6  | Paradise™ Ultrasound Renal Denervation System                         | 11/7/2023          | 10/01/2024      | 11/07/2026                                        | 89 FR 69218 through 69221<br>90 FR 36665 through 36669 | \$14,950.00                              | X051329                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 7  | PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter                | 12/13/2023         | 10/01/2024      | 12/13/2026                                        | 89 FR 69221 through 69225<br>90 FR 36665 through 36669 | \$6,337.50                               | 02583ZF                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 8  | Symplify Spinal™ Multi-Electrode Renal Denervation Catheter           | 11/17/2023         | 10/01/2024      | 11/17/2026                                        | 89 FR 69225 through 69228<br>90 FR 36665 through 36669 | \$10,400.00                              | X05133A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 9  | TriClip™ G4                                                           | 04/01/2024         | 10/01/2024      | 04/01/2027                                        | 89 FR 69228 through 69230<br>90 FR 36665 through 36669 | \$26,000.00                              | 02UJ3IZ                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 10 | VADER® Pedicle System                                                 | 02/26/2024         | 10/01/2024      | 02/26/2027                                        | 89 FR 69230 through 69236<br>90 FR 36665 through 36669 |                                          | XRH60FA, XRH63FA, XRH64FA, XRH70FA, XRH73FA, XRH74FA, XRH80FA, XRH83FA, XRH84FA, XRH1A0FA, XRH1A3FA, XRH1A4FA, XRH80FA, XRH83FA, XRH84FA, XRH1C0FA, XRH1C3FA, XRH1C4FA, XRH1D0FA, XRH1D3FA, or XRH1D4FA in combination with one of the following:<br>M46.20, M46.22, M46.23, M46.24, M46.25, M46.26, M46.27, M46.30, M46.32, M46.33, M46.34, M46.35, M46.36, M46.37, M46.39, M46.40, M46.42, M46.43, M46.44, M46.45, M46.46, M46.47, M46.49, M46.50, M46.51, M46.52, M46.53, M46.54, M46.55, M46.56, M46.57, M46.59, M46.80, M46.82, M46.83, M46.84, M46.85, M46.86, M46.87, M46.89, M46.90, M46.92, M46.93, M46.94, M46.95, M46.96, M46.97, or M46.99 |
| 11 | ZEVERTER™ (cefiboprole medocardi); ARSSSI and C-ARP Indications       | 09/30/2024         | 10/01/2024      | 09/30/2027                                        | 89 FR 69236 through 69238<br>90 FR 36665 through 36669 | \$28,242.50                              | XW0335A or XW0435A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

|    | Technology                                                            | Newness Start Date | NTAP Start Date | 3-year Anniversary Date of Entry onto U.S. Market | Previous Final Rule Citations                          | Proposed Maximum NTAP Amount for FY 2027 | Coding Used to Identify Cases Eligible for NTAP                                                                                                                                     |
|----|-----------------------------------------------------------------------|--------------------|-----------------|---------------------------------------------------|--------------------------------------------------------|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 12 | ZEVITERA™ (ceftriaxone medocanyl), SAB indication                     | 09/30/2024         | 10/01/2024      | 09/30/2027                                        | 89 FR 69236 through 69238<br>90 FR 36665 through 36669 | \$16,215.00                              | XW0335A or XW0435A in combination with R78.81 (in combination with B95.61 or B95.62)                                                                                                |
| 13 | CASGEVITY™ (exagamglogene autotemcel); Sickle Cell Disease indication | 12/08/2023         | 10/01/2024      | 12/08/2026                                        | 89 FR 69128 through 69135<br>90 FR 36665 through 36669 | \$1,650,000.00                           | XW13318 or XW14318 in combination with one of the following: D57.1, D57.20, D57.40, D57.42, D57.44, or D57.80                                                                       |
| 14 | HEPZATUM KIT (melphalan for injection)/hepatic delivery system        | 01/08/2024         | 10/01/2024      | 01/08/2027                                        | 89 FR 69158 through 69170<br>90 FR 36665 through 36669 | \$118,625.00                             | XW053T9 in combination with 5A1C00Z                                                                                                                                                 |
| 15 | LYFGENIA™ (lovotibeglogene autotemcel)                                | 12/08/2023         | 10/01/2024      | 12/08/2026                                        | 89 FR 69188 through 69196<br>90 FR 36665 through 36669 | \$2,325,000.00                           | XW133H9 or XW143H9                                                                                                                                                                  |
| 16 | 4WEB Medical Ankle Truss System                                       | 01/31/2025         | 10/01/2025      | 01/31/2028                                        | 90 FR 36770 through 36773                              | \$15,275.00                              | XRGJ0B9, XRGK0B9, XRGJ0B9, or XRGJ0B9                                                                                                                                               |
| 17 | AeroPace® System                                                      | 12/04/2024         | 10/01/2025      | 12/04/2027                                        | 90 FR 36773 through 36776                              | \$23,650.90                              | X2H13XB                                                                                                                                                                             |
| 18 | AGENT™ Pacilitaxel-Coated Balloon Catheter                            | 02/29/2024         | 10/01/2025      | 02/29/2027                                        | 90 FR 36776 through 36779                              |                                          | XW013HA, XW013JA, XW013KA, XW013LA, XW0K3HA, XW0K3JA, XW0K3KA, XW0K3LA, XW0L3HA, XW0L3JA, XW0L3KA, XW0L3LA, XW0M3HA, XW0M3JA, XW0M3KA, or XW0M3LA                                   |
| 19 | allapump® system                                                      | 12/20/2024         | 10/01/2025      | 12/20/2027                                        | 90 FR 36779 through 36781                              | \$21,450.00                              | 0W1G3J6 in combination with 0JH80YZ                                                                                                                                                 |
| 20 | aprevo®-C cervical interbody fusion device                            | 11/15/2024         | 10/01/2025      | 11/15/2027                                        | 90 FR 36781 through 36784                              | \$21,125.00                              | XRG10RB, XRG13RB, XRG14RB, XRG20RB, XRG23RB, XRG24RB, XRG40RB, XRG43RB, or XRG44RB                                                                                                  |
| 21 | CERAMENT®-G (open fracture indication)                                | 03/13/2024         | 10/01/2025      | 03/13/2027                                        | 90 FR 36784 through 36786                              | \$5,687.50                               | XW0V0P7 without any of the ICD-10-CM diagnosis codes in category M86                                                                                                                |
| 22 | Emily's Care Nourish Test System (Model 1)                            | 05/03/2024         | 10/01/2025      | 05/03/2027                                        | 90 FR 36786 through 36792                              |                                          | XXEZXAB in combination with one of the following: P05.01, P05.02, P05.03, P05.04, P05.05, P05.11, P05.12, P05.13, P05.14, P05.15, P07.00, P07.01, P07.02, P07.03, P07.14, or P07.15 |
| 23 | Esprit™ BTK Everolimus Eluting Resorbable Scaffold System             | 04/26/2024         | 10/01/2025      | 04/26/2027                                        | 90 FR 36792 through 36795                              | \$6,972.50                               | X27P3TA, X27Q3TA, X27R3TA, X27S3TA, X27T3TA, or X27U3TA                                                                                                                             |
| 24 | EUROPA™ Posterior Cervical Fusion System                              | 11/19/2024         | 10/01/2025      | 11/19/2027                                        | 90 FR 36795 through 36798                              |                                          | XRH10GB, XRH13GB, XRH14GB, XRI120GB, XRI123GB, XRI124GB, XRH40GB, XRH43GB, XRH44GB, XRH60GB, XRH63GB, or XRH64GB                                                                    |
| 25 | iFuse TORQ TNY™ Implant System                                        | 08/19/2024         | 10/01/2025      | 08/19/2027                                        | 90 FR 36798 through 36803                              | \$80,548.00                              | XRGEMIB, XRGEMIB, XRGF0IB, XRGF3HB, XNSN0HB, XNSN3HB, XNSP0IB, XNSP3IB, XNLI60IB, XNH63HB, XNH70HB, or XNH73HB                                                                      |
| 26 | Merit Wrapbody® Cell Impermeable Endoprosthesis (CIE)                 | 01/02/2025         | 10/01/2025      | 01/02/2028                                        | 90 FR 36803 through 36806                              | \$4,135.95                               | X27535B, X27635B, X27735B, X27835B, X27935B, X27A35B, X27B35B, X27C35B, X27D35B, or X27E35B                                                                                         |



|    | Technology                                            | Newness Start Date | NTAP Start Date | 3-year Anniversary Date of Entry into U.S. Market | Previous Final Rule Citations | Proposed Maximum NTAP Amount for FY 2027 | Coding Used to Identify Cases Eligible for NTAP                                                                                                                |
|----|-------------------------------------------------------|--------------------|-----------------|---------------------------------------------------|-------------------------------|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 27 | <i>Minima Sient System</i>                            | 08/28/2024         | 10/01/2025      | 08/28/2027                                        | 90 FR 36806 through 36808     | \$22,685.00                              | X27339B, X27439B, X27W39B, or X27X39B                                                                                                                          |
| 28 | <i>M301 Continuous Compartmental Pressure Monitor</i> | 04/29/2025         | 10/01/2025      | 04/29/2028                                        | 90 FR 36808 through 36810     | \$2,112.50                               | XX2F3W9                                                                                                                                                        |
| 29 | <i>PBC Separator with Seflux AST System</i>           | 02/15/2024         | 10/01/2025      | 02/15/2027                                        | 90 FR 36810 through 36813     | \$87.78                                  | XXE5XY9                                                                                                                                                        |
| 30 | <i>restor3d TID:4L™ Fusion Cage</i>                   | 03/24/2025         | 10/01/2025      | 03/24/2028                                        | 90 FR 36817 through 36819     | \$18,196.75                              | XRGK0C-A, XRGW0C-A, XRGJ0C-A, or XRG10C-A                                                                                                                      |
| 31 | <i>ShortCur™</i>                                      | 09/27/2024         | 10/01/2025      | 09/27/2027                                        | 90 FR 36819 through 36821     | \$9,750.00                               | X28F3VA                                                                                                                                                        |
| 32 | <i>The WISE CRT System</i>                            | 04/11/2025         | 10/01/2025      | 04/11/2028                                        | 90 FR 36821 through 36823     | \$41,145.00                              | X2HN37B in combination with XHH80HB                                                                                                                            |
| 33 | <i>TriVivity Test</i>                                 | 01/10/2025         | 10/01/2025      | 01/10/2028                                        | 90 FR 36823 through 36826     | \$243.75                                 | XXE5XBB                                                                                                                                                        |
| 34 | <i>VITEK® REVEAL™ AST System</i>                      | 10/21/2024         | 10/01/2025      | 10/21/2027                                        | 90 FR 36826 through 36829     | \$81.25                                  | XXE5X4A                                                                                                                                                        |
| 35 | <i>EMBLAVEO™ (aztreonam-avibactam)</i>                | 02/07/2025         | 10/01/2025      | 02/07/2028                                        | 90 FR 36829 through 36831     | \$9,000.68                               | XW033PB or XW043PB                                                                                                                                             |
| 36 | <i>CONTEPO™ (fosfomycin)</i>                          | 10/22/2025         | 01/01/2026      | 10/22/2028                                        | 90 FR 36831 through 36834     | \$8,775.00                               | XW033WB or XW043WB                                                                                                                                             |
| 37 | <i>AURUMYN™ (lipoyest injection)</i>                  | 11/01/2024         | 10/01/2025      | 11/01/2027                                        | 90 FR 36680 through 36687     | \$28,600.00                              | XW033QB or XW043QB                                                                                                                                             |
| 38 | <i>BREYANZI® (disocarbogene mardience)</i>            | 03/14/2024         | 10/01/2025      | 03/14/2027                                        | 90 FR 36687 through 36695     |                                          | XW033N7 or XW043N7 in combination with one of the following: C83.00, C83.01, C83.02, C83.03, C83.04, C83.05, C83.06, C83.07, C83.08, C83.09, C91.10, or C91.12 |
| 39 | <i>GRAFAPEX™ (preovifan)</i>                          | 01/21/2025         | 10/01/2025      | 01/21/2028                                        | 90 FR 36707 through 36717     | \$316,860.05                             | XW03388 or XW04388                                                                                                                                             |
| 40 | <i>IMDELLTRA® (torlatamab-dlile)</i>                  | 03/16/2024         | 10/01/2025      | 03/16/2027                                        | 90 FR 36717 through 36727     | \$7,117.50                               | XW033NA or XW043NA                                                                                                                                             |
| 41 | <i>TECEFLRA® (tiamitresgene autoleuce)</i>            | 08/01/2024         | 10/01/2025      | 08/01/2027                                        | 90 FR 36753 through 36761     | \$472,550.00                             | XW03368 or XW04368                                                                                                                                             |

determined to be substantially similar to such technologies, for which we are proposing to discontinue making new technology add-on payments for FY 2027 because they are no longer “new” for purposes of new technology add-on payments because the 3-year anniversary date of the product’s entry onto the U.S. market occurs before April 1, 2027. This table also lists one technology that was first approved for new technology add-on payments in FY 2026, for which we are proposing to discontinue making new technology add-on payments for FY 2027 because it is no longer “new” for purposes of new technology add-on payments because the 3-year anniversary date of the product’s entry onto the U.S. market occurs before October 1, 2026. For all technologies, this table also presents the newness start date, new technology add-on payment start date, the 3-year anniversary date of the product’s entry onto the U.S. market, and relevant final rule citations from prior fiscal years. We refer readers to the cited final rules in the table for a complete discussion of each new technology add-on payment application and the coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We note that while we are proposing to discontinue new technology add-on payments for FY 2027 for the Ceribell Status Epilepticus Monitor, Ceribell, Inc. is seeking new technology add-on payments for the Ceribell Delirium Monitor System for FY 2027 (as discussed in section II.E.6. of the preamble of this proposed rule), which is also identified by the ICD–10–PCS procedure code XX20X89 (Monitoring of brain electrical activity, computer-aided detection and notification, new technology group 9). In order to identify cases using the ICD–10–PCS procedure code XX20X89 related to the Ceribell Delirium Monitor System and not the

Ceribell Status Epilepticus Monitor, which would no longer be new, we are proposing to exclude cases that report the ICD–10–CM diagnosis codes that we believe would identify patients with status epilepticus in combination with the ICD–10–PCS procedure code XX20X89. Please see Table 10.2.—Ceribell Delirium Monitor System, associated with this proposed rule, for the list of ICD–10–CM diagnosis codes that we believe would identify patients with status epilepticus, which we propose to exclude from new technology add-on payment when reported in combination with ICD–10–PCS procedure code XX20X89. We are inviting public comments on our proposal to exclude cases reporting these ICD–10–CM diagnosis codes in combination with the ICD–10–PCS procedure code XX20X89, for purposes of the new technology add-on payment for FY 2027, if approved.

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36666 through 36671), in response to public comments, including from the applicant for the SAINT Neuromodulation System, that requested that CMS recognize a delay in commercial availability of the technology to April 5, 2024, and subsequently extend new technology add-on payment for the SAINT Neuromodulation System for FY 2026, we questioned whether, where the applicant asserts a date of commercial availability that occurred after the new technology add-on payment for the technology began, it would be appropriate to instead consider the beginning of the newness period to commence with the start of the technology’s new technology add-on payment. We noted that regardless of whether we considered the beginning of the newness period to commence for SAINT Neuromodulation System on April 5, 2024; a date that reflects the start of the technology’s new technology

add-on payment in FY 2024; or a date in between, the three-year anniversary date would occur after April 1, 2026, and, therefore, the technology was considered new for FY 2026.

As discussed in greater detail previously in this section, after further consideration, we are proposing that we may consider a documented delay in the beginning of a technology’s newness period due to commercial availability only until the new technology add-on payment becomes effective. Specifically, for a technology that is not yet available for sale when its new technology add-on payment becomes effective, we would consider the newness period to begin on September 30 preceding the start of the new technology add-on payment for the technology.

As such, consistent with this proposal, because the new technology add-on payment for SAINT Neuromodulation System became effective on October 1, 2023, we consider the beginning of the newness period for SAINT Neuromodulation System to commence on September 30, 2023. As the SAINT Neuromodulation System was first approved for new technology add-on payments in FY 2024, we continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether this technology would still be considered “new” for purposes of new technology add-on payments. Because we consider the beginning of the newness period to commence on September 30, 2023, the three-year anniversary date would occur before April 1, 2027, and the technology would no longer be considered new for FY 2027.

We are inviting public comments on our proposals to discontinue new technology add-on payments for FY 2027 for the technologies listed in Table II.E.–02 of the preamble of this proposed rule.

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**TABLE I.I.E.-02: PROPOSED DISCONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2026 NEW TECHNOLOGY ADD-ON PAYMENTS NO LONGER CONSIDERED NEW FOR FY 2027**

| Technology                                                                                                                                                                                                                             | Newness Start Date | NTAP Start Date | 3-year Anniversary Date of Entry onto U.S. Market | Previous Final Rule Citations                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-----------------|---------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>PROPOSED DISCONTINUATION OF TECHNOLOGIES FIRST APPROVED FOR NEW TECHNOLOGY ADD-ON PAYMENTS PRIOR TO FY 2025 THAT ARE NO LONGER CONSIDERED NEW FOR FY 2027 BECAUSE THE 3-YEAR ANNIVERSARY DATE WILL OCCUR PRIOR TO APRIL 1, 2027</b> |                    |                 |                                                   |                                                                                     |
| 1 CYTALUX® (ipagofolactamine) (lung indication)                                                                                                                                                                                        | 06/05/2023         | 10/01/2023      | 06/05/2026                                        | 88 FR 58810 through 58818<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| 2 EPKINLY™ (epcoritamab-bvsp) and COLUMMIT™ (gloftamab-gxbm)                                                                                                                                                                           | 05/19/2023         | 10/01/2023      | 05/19/2026                                        | 88 FR 58818 through 58835<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| 3 Aveir™ AR Leadless Pacemaker                                                                                                                                                                                                         | 06/29/2023         | 10/01/2023      | 06/29/2026                                        | 88 FR 58919 through 58923<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| 4 Aveir™ Dual-Chamber Leadless Pacemaker                                                                                                                                                                                               | 06/29/2023         | 10/01/2023      | 06/29/2026                                        | 88 FR 58923 through 58925<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| 5 Certibell Status Epilepticus Monitor                                                                                                                                                                                                 | 05/23/2023         | 10/01/2023      | 05/23/2026                                        | 88 FR 58927 through 58930<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| 6 DETOUR System                                                                                                                                                                                                                        | 06/07/2023         | 10/01/2023      | 06/07/2026                                        | 88 FR 58930 through 58932<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| 7 DefenCath® (taurolidine/heparin)                                                                                                                                                                                                     | 11/15/2023         | 01/01/2024      | 11/15/2026                                        | 88 FR 58942 through 58944<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| 8 Phagenyx® System                                                                                                                                                                                                                     | 04/12/2023         | 10/01/2023      | 04/12/2026                                        | 88 FR 58935 through 58937<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| 9 REZZAYO™ (re-afungin for injection)                                                                                                                                                                                                  | 07/19/2023         | 10/01/2023      | 07/19/2026                                        | 88 FR 58944 through 58946<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| 10 SAINT Neuromodulation System                                                                                                                                                                                                        | 09/30/2023         | 10/01/2023      | 09/30/2026                                        | 88 FR 58937 through 58939<br>89 FR 69120 through 69126<br>90 FR 36670 through 36673 |
| 11 TOPST™ System                                                                                                                                                                                                                       | 06/15/2023         | 10/01/2023      | 06/15/2026                                        | 88 FR 58940 through 58942<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| 12 XACDURO® (sulbactam/durlobactam)                                                                                                                                                                                                    | 05/23/2023         | 10/01/2023      | 05/23/2026                                        | 88 FR 58946 through 58948<br>89 FR 69120 through 69126<br>90 FR 36665 through 36669 |
| <b>PROPOSED DISCONTINUATION OF TECHNOLOGY FIRST APPROVED FOR NEW TECHNOLOGY ADD-ON PAYMENTS IN FY 2026 THAT IS NO LONGER CONSIDERED NEW FOR FY 2027 BECAUSE THE 3-YEAR ANNIVERSARY DATE WILL OCCUR PRIOR TO OCTOBER 1, 2026</b>        |                    |                 |                                                   |                                                                                     |
| 1 RECELL® Autologous Cell Harvesting Device                                                                                                                                                                                            | 06/07/2023         | 10/01/2025      | 06/07/2026                                        | 90 FR 36813 through 36817                                                           |

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## 5. Proposed FY 2027 Applications for New Technology Add-On Payments (Traditional Pathway)

As discussed previously, as finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990) and subsequently updated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36662 through 36664), we publicly post online applications for new technology add-on payment beginning with FY 2024 applications. As noted in these final rules, while we are continuing to provide discussion of the concerns or issues we identified with respect to applications submitted under the traditional pathway, we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the newness, cost, and substantial clinical improvement criteria. We refer readers to <https://mearis.cms.gov/public/publications/ntap> for the publicly posted FY 2027 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted), including tables listing the ICD-10-CM codes, ICD-10-PCS codes, and/or MS-DRGs related to the analyses of the cost criterion for certain technologies for the FY 2027 new technology add-on payment applications.

We received 15 applications for new technology add-on payments for FY 2027 under the new technology add-on payment traditional pathway. In accordance with the regulations under § 412.87(f), applicants for FY 2027 new technology add-on payments must have received FDA marketing authorization

by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As previously discussed, beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 and FY 2025 IPPS/LTCH PPS final rules (88 FR 58948 through 58958; 89 FR 69242 through 69245). Of the 15 applications received under the traditional pathway, 3 applicants were not eligible for consideration for new technology add-on payment because they did not meet these requirements, and 4 applicants withdrew their applications prior to the issuance of this proposed rule. We are addressing the remaining 8 applications.

Typically, in the annual proposed rule, we provide a summary of each traditional pathway application and describe any concerns we may have regarding whether the technology meets a specific new technology add-on payment criterion. In this proposed rule, for technologies that have already received FDA marketing authorization, we are making a proposal to approve or disapprove each of these applications for new technology add-on payment. We have stated in prior rulemaking that we do not believe it is appropriate for CMS

to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA makes a determination as to whether the medical service or technology is safe and effective (86 FR 45047). Therefore, we are not making a proposal approve or disapprove applications for technologies that have not yet received FDA marketing authorization for new technology add-on payment.

## a. COBENFY™ (Xanomeline and Trospium Chloride)

Bristol Myers Squibb submitted a FY 2027 application for new technology add-on payments for COBENFY™. According to the applicant, COBENFY™ is an oral combination drug consisting of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, indicated for the treatment of schizophrenia in adults. COBENFY™ has 3 approved dose strengths (50 mg/20 mg, 100 mg/20 mg, and 125 mg/30 mg) in capsule form. The applicant stated the per-day treatment cost is the same across all dosages and that the average inpatient length of stay for patients taking COBENFY™ is 7.5 days. We note that the applicant submitted a FY 2026 new technology add-on payment application for this technology, which was not approved, as discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36695 through 36702).

The following table provides an overview of the new technology add-on payment application for COBENFY™ and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251006PD218>.

|                                                   |                               | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                 | Preliminary CMS Assessment                        |
|---------------------------------------------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Unique ICD-10-PCS code(s)</b>                  |                               | XW0DXVB                                                                                                                                                                                                                                                                                                                                                                              | No concerns.                                      |
| <b>Newness</b>                                    | <b>Newness Period</b>         | NDA approved on September 26, 2024, for the treatment of schizophrenia in adults.<br><br>Commercial availability delay to October 9, 2024.                                                                                                                                                                                                                                           | Newness date:<br>October 9, 2024.                 |
|                                                   | <b>Substantial Similarity</b> | Uses a new mechanism of action.                                                                                                                                                                                                                                                                                                                                                      | Not substantially similar to existing treatments. |
| <b>Cost Criterion</b>                             |                               | 23,422 claims mapping to 9 MS-DRGs, with 93.4% of claims mapping to MS-DRG 885 (Psychoses).<br><br>Final inflated average case-weighted standardized charge per case of \$48,938 exceeded the average case-weighted threshold amount of \$47,224.                                                                                                                                    | Meets cost criterion.                             |
| <b>Substantial Clinical Improvement Criterion</b> |                               | Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments.<br><br>Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.<br><br>Provided 5 published and 2 unpublished studies assessing the technology, and other information. | See following discussion.                         |

#### Newness Criterion

Regarding substantial similarity, based on information available at the time of this proposed rule and as previously stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36697), we agree with the applicant that COBENFY™ uses a unique mechanism of action, because it is the first schizophrenia treatment for adults to target muscarinic receptors in the brain by combining the muscarinic agonist, xanomeline, and the muscarinic antagonist, trospium chloride, unlike typical and atypical antipsychotics currently used to treat schizophrenia which antagonize dopamine receptors. Therefore, based on information available at the time of this proposed rule, we believe that COBENFY™ is not substantially similar to existing treatment options and meets the newness criterion. As discussed in the FY 2026 IPPS/LTCH PPS final rule, we consider the beginning of the newness period to commence on October 9, 2024, the date on which COBENFY™ became commercially available.

We are inviting public comments on whether COBENFY™ is substantially similar to existing technologies and whether COBENFY™ meets the newness criterion.

#### Cost Criterion

Regarding the cost criterion, we agree with the applicant that the technology meets the cost criterion. We are inviting public comments on whether COBENFY™ meets the cost criterion.

#### Substantial Clinical Improvement Criterion

Regarding substantial clinical improvement, we also received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for COBENFY™, which we are summarizing in this section.

*Comment:* The applicant submitted a public comment in response to questions posed at the New Technology Town Hall meeting. With regard to a question asking if COBENFY™ is considered to be an antipsychotic, the applicant stated that the FDA label for COBENFY™ does not use the term antipsychotic in the indication section. The applicant stated that the indication section states that COBENFY™ is a combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, indicated for the treatment of schizophrenia in adults.<sup>25</sup> According to the applicant, this distinction is due to FDA's recent shift toward a mechanism-based nomenclature, rather than a determination regarding COBENFY™'s therapeutic role. The applicant also stated that the term antipsychotic is based on both pharmacology and clinical use, encompassing drugs used for a range of psychiatric conditions

beyond psychosis. The applicant further noted that FDA recognized COBENFY™'s role as an antipsychotic when the agency described the drug as the first antipsychotic drug approved to treat schizophrenia that targets cholinergic receptors as opposed to dopamine receptors, which has long been the standard of care.<sup>26</sup> Additionally, the applicant stated that, in recognition of COBENFY™'s unique role as an antipsychotic, the United States Pharmacopeia Drug Classification (USP DC) 2025 established a new Antipsychotics, Other class within the Antipsychotics Category to accommodate novel medicines like COBENFY™ that do not fit into the traditional typical or atypical antipsychotic classes due to distinct pharmacology. Per the applicant, COBENFY™'s inclusion in the Antipsychotics, Other class highlights its differentiated mechanism while maintaining its place among other antipsychotic therapies as a treatment for schizophrenia.

With regard to a question asking how quickly COBENFY™ takes effect, the applicant stated that although the EMERGENT studies assessed the primary endpoint at 5 weeks, the studies observed meaningful clinical effects much earlier. The applicant

<sup>25</sup> Bristol Myers Squibb Company. (2024). *Highlights of Prescribing Information: COBENFY™ (xanomeline and trospium chloride) capsules, for oral use*. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/216158s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216158s000lbl.pdf).

<sup>26</sup> U.S. Food and Drug Administration. (2024, September 26). *FDA Approves Drug with New Mechanism of Action for Treatment of Schizophrenia* [Press release]. <https://www.fda.gov/news-events/press-announcements/fda-approves-drug-new-mechanism-action-treatment-schizophrenia>.

further added that the studies found significant reductions in Positive and Negative Syndrome Scale (PANSS) total score (nominal p-value) within 2 weeks (the first scheduled assessment across all 3 trials), demonstrating that COBENFY™'s therapeutic benefit appears well before the primary endpoint. In addition, the applicant stated that this clinically observable effect time period complements care in the inpatient setting, where patients with schizophrenia often require 7 to 14 days of treatment, compared to the more standard 3 to 4 days for other mental health conditions.

With regard to a question inquiring whether the clinical trials included case management or patient support to ensure compliance or if there was qualitative evidence that efficacy alone drives compliance, the applicant stated that clinical trials typically provide a more controlled environment with additional patient support, which often leads to higher compliance compared to adherence and persistence observed in real-world settings; a pattern, the applicant noted, that is likely true for COBENFY™ as well. The applicant noted that it drew the adherence and persistence data presented at the New Technology Town Hall from a large, observational, real-world administrative claims database of patients prescribed COBENFY™ in routine clinical practice, without extra monitoring or support beyond standard care.<sup>27</sup> The applicant also stated that early real-world data for COBENFY™ show encouraging adherence and persistence: over 80 percent of patients remained on therapy through month 4, and 72 percent met the established adherence metric during the follow-up, all while receiving only standard clinical care (Cutler et al., 2025). Additionally, the applicant stated that, although these findings reflect very early treatment patterns less than a year after COBENFY™'s market introduction, this strong adherence signal is particularly meaningful, as consistent use of antipsychotic medications is closely linked to lower rates of relapse, preventable hospitalizations, and emergency department visits in individuals with schizophrenia. Per the applicant, these early results suggest that COBENFY™ may offer meaningful benefits in real-world settings by supporting sustained treatment and potentially reducing the burden of acute

healthcare utilization. Lastly, the applicant noted that CMS has designated adherence to antipsychotic medications as a clinical quality measure for healthcare providers.<sup>28</sup>

*Response:* We thank the applicant for its comment. After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether COBENFY™ meets the substantial clinical improvement criterion.

In support of its assertions that COBENFY™ provides a treatment option for a patient population unresponsive to or ineligible for currently available therapies and that COBENFY™ improves clinical outcomes, the applicant provided studies that were also included in its FY 2026 new technology add-on payment application in addition to three new references: a post-hoc analysis and two posters.<sup>29 30 31</sup> In its FY 2027 new technology add-on payment application, the applicant submitted six similar claims to those provided in its FY 2026 new technology add-on payment application, as well as additional claims stating: COBENFY™ offers a treatment option for schizophrenia patients with extensive prior antipsychotic use, COBENFY™ shows strong real-world persistence and adherence, and COBENFY™ shows superior effectiveness.

After review of this information, we continue to question whether COBENFY™ provides a treatment option for a patient population unresponsive to or ineligible for currently available therapies or

improves clinical outcomes relative to existing technologies.

With regards to a new claim in its FY 2027 new technology add-on payment application that COBENFY™ offers a treatment option for schizophrenia patients with extensive prior antipsychotic use, we note that this claim does not identify a patient population for which COBENFY™ could be used that is unresponsive to or ineligible for other available treatments since patients with prior antipsychotic use could still try other antipsychotics such as clozapine, which is indicated for patients who do not respond to other antipsychotics. We also question whether the evidence provided for this claim demonstrates the applicant's assertion. The applicant provided Cutler et al. (2025), a retrospective observational study of claims data for adults with schizophrenia in the U.S. before and after COBENFY™ initiation. Because Cutler et al. (2025) relied upon administrative claims data, we cannot be sure whether patients actually took the prescribed oral medication(s). Consequently, we are unable to determine whether all patients treated in this study had extensive prior antipsychotic use or if the patients actually took COBENFY™. Also, the study measured medication adherence at 60 and 90 days following COBENFY™ treatment initiation. However, we note that injectable antipsychotics, which patients adhere to because they are long-acting drugs that require professional administration, are typically administered at intervals of 2 to 12 weeks.<sup>32</sup> Therefore, we are concerned that measuring adherence at 60 and 90 days may be inadequate to accurately assess differences between COBENFY™ and existing schizophrenia treatments. We also question long-term adherence rates since the average follow-up was only 2.6 months. Finally, we are concerned that Cutler et al. (2025) does not demonstrate that COBENFY™ has improved clinical outcomes compared to other therapies because this evidence does not include a comparison of adherence data to existing schizophrenia treatments.

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36702), after consideration of public comments, we continued to have concerns as to whether COBENFY™ meets the substantial clinical improvement criterion, including with respect to the

<sup>28</sup> Merit-Based Incentive Payment System Clinical Quality Measures #383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia. Centers for Medicare and Medicaid Services. Retrieved December 16, 2025 from [https://qpp.cms.gov/docs/QPP\\_quality\\_measure\\_specifications/CQM-Measures/2025\\_Measure\\_383\\_MIPSCQM.pdf](https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2025_Measure_383_MIPSCQM.pdf).

<sup>29</sup> Cutler, A.J., Zhong, Y., Gillard, K., Appio, J., Gao, C., Laliberté, F., Rubio, J.M. *Real-World Use of Xanomeline-Trospium in Schizophrenia: Patient Characteristics and Antipsychotic Treatment Patterns*. Presentation at Psych Congress, September 17–21, 2025, San Diego, CA.

<sup>30</sup> Horan W.P., Targum S.D., Claxton A., Kaul I., Yohn S.E., Marder S.R., Miller A.C., Brannan S.K. Efficacy of KarXT on negative symptoms in acute schizophrenia: A post hoc analysis of pooled data from 3 trials. *Schizophr Res.* 2024 Dec;274:57–65. <https://doi.org/10.1016/j.schres.2024.08.001>.

<sup>31</sup> Hickey, C., Sidovar, M., Garcia, A., Kramer, K., Chang, J.A., Kupas, K., Telukuntla, V., Cutler, A.J. *Comparative Efficacy, Safety, and Tolerability of Xanomeline and Trospium Chloride versus Eight Atypical Antipsychotics for the Acute Treatment of Adults with Schizophrenia—A Network Meta-Analysis*. Presentation at the 2025 Annual Congress of the Schizophrenia International Research Society (SIRS), March 29–April 2, 2025, Chicago, Illinois.

<sup>27</sup> Cutler, A.J., Zhong, Y., Gillard, K., Appio, J., Gao, C., Laliberté, F., Rubio, J.M. *Real-World Use of Xanomeline-Trospium in Schizophrenia: Patient Characteristics and Antipsychotic Treatment Patterns*. Presentation at Psych Congress, September 17–21, 2025, San Diego, CA.

<sup>32</sup> Stroup, T.S. & Marder, S. (2025). Schizophrenia in adults: Maintenance therapy and side effect management. *UpToDate*. Retrieved October 7, 2025, from <https://www.uptodate.com/contents/schizophrenia-in-adults-maintenance-therapy-and-side-effect-management>.

applicant's claims that COBENFY™ may be an effective treatment option for patients experiencing disruptive negative symptoms and that COBENFY™ is a valuable option for patients who respond inadequately to current treatments. The applicant submitted similar claims in its FY 2027 new technology add-on payment application, but did not provide additional supporting evidence. Therefore, we continue to question whether the evidence provided for these claims in the FY 2027 new technology add-on payment application demonstrates that COBENFY™ offers a treatment option for patients unresponsive to or ineligible for other therapies, without data supporting that other antipsychotics cannot be used in patients with negative symptoms or who have not responded to other antipsychotics.

With respect to the assertion that COBENFY™ provides improved clinical outcomes relative to previously available therapies by improving symptom response and reducing metabolic side effects compared to several atypical antipsychotics, the applicant provided Hickey et al. (2025), a network meta-analysis poster, which used data from 58 randomized controlled trials lasting between 4 and 6 weeks and indirectly compared COBENFY™ to aripiprazole, cariprazine, olanzapine, risperidone, brexpiprazole, quetiapine, clozapine, and lumateperone. However, the poster does not consistently show a statistically significant difference in favor of COBENFY™ (such as with respect to PANSS response, change from baseline weight, and sedation). We also note that the poster did not provide comparison to typical antipsychotics or other atypical antipsychotics, such as olanzapine/samidorphan, which includes samidorphan to reduce weight gain. For these reasons, we question whether this study demonstrates COBENFY™ improves clinical outcomes compared to other available

therapies. Additionally, we note that Hickey et al. (2025) found that COBENFY™ had statistically significant higher odds of discontinuation due to all causes compared to all comparators except cariprazine, for which results were unfavorable but not statistically significant. As a result, we further question the applicant's claim that COBENFY™ demonstrates improved persistence and adherence compared to currently available treatments.

Finally, we note that in support of its assertion of improved clinical outcomes compared to previously available therapies, the applicant also provided four claims in its FY 2027 new technology add-on payment application that were similar to the claims provided in its FY 2026 new technology add-on payment application. We note the only additional evidence submitted for these claims in the applicant's FY 2027 new technology add-on payment application was Horan et al. (2024), a post-hoc analysis of pooled data from the three 5-week EMERGENT studies, which was also the only evidence provided for the claim regarding long-term reduction in symptoms and a persistently well-tolerated side effect profile. However, the studies included in this analysis compared COBENFY™ to placebo, and therefore, we are unable to assess whether there is a long term reduction of symptoms and favorable side effect profile compared to existing schizophrenia treatments. In addition, we question this claim given the short duration of the trials and the lack of discussion on side effects in the article. Lastly, since the applicant did not submit evidence comparing COBENFY™ to other available therapies with regard to efficacy, safety, or discontinuation rates, we continue to question whether the evidence demonstrates improved clinical outcomes compared to previously available therapies with respect to these claims, as stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36702).

After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we are unable to determine that COBENFY™ represents a substantial clinical improvement over existing technologies, and therefore, we are proposing to disapprove new technology add-on payments for COBENFY™ for FY 2027.

We are inviting public comments on whether COBENFY™ meets the substantial clinical improvement criterion and our proposal to disapprove new technology add-on payments for COBENFY™ for FY 2027.

#### b. Command Center Electronic Glycemic Management System

Glytec, LLC submitted a FY 2027 application for new technology add-on payments for Command Center Electronic Glycemic Management System (Command Center). According to the applicant, Command Center is an electronic medical record (EMR)-integrated cloud-based software designed to maintain blood glucose in hospitalized patients by recommending personalized insulin dosing. According to the applicant, the technology utilizes inputs collected from EMRs to direct ongoing insulin dosage management and daily monitoring related glycemic variables (such as labs and diet) during an inpatient stay until insulin is discontinued or the patient is sent home. Per the applicant, direct per-patient charge for the use of Command Center follows a subscription model.

The following table provides an overview of the new technology add-on payment application for Command Center and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251005YD7PG>.

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|                                                   |                               | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Preliminary CMS Assessment                                     |
|---------------------------------------------------|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| <b>Unique ICD-10-PCS code(s)</b>                  |                               | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | N/A.                                                           |
| <b>Newness Criterion</b>                          | <b>Newness Period</b>         | 510(k) clearance for Glytec Glucomander on August 4, 2017, to evaluate current as well as cumulative patient blood glucose values coupled with patient information including age, weight, and height, and, based on the aggregate of these measurement parameters, whether one or many, recommend an IV dosage of insulin, glucose or saline or a subcutaneous basal and bolus insulin dosing recommendation to adjust and maintain the blood glucose level towards a configurable physician-determined target range. It is indicated for use in adults and pediatric (ages 2 to 17 years) patients.                                                                                                                                                     | Newness date: August 4, 2017.<br><br>See following discussion. |
|                                                   | <b>Substantial Similarity</b> | Uses a new mechanism of action.<br><br>Treats a new disease or patient population.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | See following discussion.                                      |
| <b>Cost Criterion</b>                             |                               | 845 claims mapping to 4 MS-DRGs, with 40.12 percent of claims mapping to MS-DRG 640 (Miscellaneous Disorders of Nutrition, Metabolism, Fluids, and Electrolytes with MCC).<br><br>The final inflated average case-weighted standardized charge per case was not provided.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | See following discussion.                                      |
| <b>Substantial Clinical Improvement Criterion</b> |                               | Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments.<br><br>Assertion #2: The technology offers the ability to diagnose a medical condition in a patient population where that condition is currently undetectable or earlier than allowed by currently available methods, and that use of the technology to make a diagnosis affects the management of the patient.<br><br>Assertion #3: The technology significantly improves clinical outcomes relative to services or technologies previously available.<br><br>Provided 1 published study assessing the technology, 3 published and 5 unpublished studies assessing precursor technologies, and other information. | See following discussion.                                      |

**BILLING CODE 4120-01-C****Newness Criterion**

Regarding the newness date, the applicant provided an FDA 510(k) clearance letter for Glytec Glucomander (K152300), dated August 4, 2017, to support its new technology add-on payment application for Command Center. Per the 510(k) summary, the predicate device for Glytec Glucomander is Glucomander™ System (K113852).<sup>33</sup> Per the applicant, Command Center was available for sale immediately after FDA marketing authorization. Therefore, the newness period for Command Center commenced on the date of FDA clearance, August 4, 2017, or earlier, as discussed further in this section. Because the 3-year anniversary date of the entry of Command Center onto the U.S. market (August 4, 2020, or earlier) occurred prior to FY 2027, we do not

believe that the device is eligible for new technology add on payments for FY 2027. Consistent with the statute and our implementing regulations, a technology is no longer considered “new” once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349). Accordingly, we are proposing to disapprove Command Center for new technology add on payments for FY 2027.

In addition, regarding substantial similarity, we question whether Command Center has the same or similar mechanism of action as existing technologies that manage glycemic dosing. The applicant stated that Command Center differs from other insulin management methods because it is an intelligent, algorithm-based analytic technology that uses multiple administrative, technical, and clinical inputs to develop an optimized insulin and glycemic management system to control glucose metabolism while minimizing hyper- and hypoglycemic

episodes. Per the applicant, glycemic management is typically performed by nurses and doctors using a paper and pencil sliding scale algorithm to estimate the amount of insulin needed based on blood glucose values. According to the applicant, while other digital glycemic management systems can be built into EMR tables or in stand-alone systems, none are as sophisticated or as well-documented as Command Center. However, we note that there are several existing software-based, EMR-integrated glycemic management systems. For example, the 2012 Glucomander™ System,<sup>34</sup> the GlucoStabilizer Insulin Dosing Calculator 3.0,<sup>35</sup> the EndoTool™ Drug

<sup>33</sup> FDA, Glucomander™ System, May 8, 2012 (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K113853>, accessed 2/9/2026).

<sup>34</sup> FDA, May 8, 2012, K113853 Glytec LLC Glucomander™ System (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K113853>, accessed 1/2/2026).

<sup>35</sup> FDA, September 15, 2014, K141321, Glucostabilizer Insulin Dosing Calculator (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K141321>, accessed 1/2/2026).



Dose Calculator,<sup>36</sup> and the EndoTool SubQ™<sup>37</sup> are all FDA-cleared glycemic management tools that monitor patient blood glucose and generate personalized insulin dosing recommendations. Therefore, we disagree with the applicant that Command Center uses a different mechanism of action compared to existing technologies to achieve a therapeutic outcome. Additionally, we disagree with the applicant that the use of Command Center involves the treatment of a different type of disease or patient population compared to existing technology. The applicant stated that Command Center will better address glycemic management needs in patients where higher degrees of blood glucose control accuracy are required, including post-coronary artery bypass graft (CABG) surgery patients, patients with diabetic ketoacidosis or hyperosmolar coma, stroke patients, pregnant patients, or children, and can be used in populations where advanced endocrinology expertise is not readily available. However, as we noted, several technologies are currently available for insulin and glycemic management for the same or similar type of disease and patient populations. Furthermore, we note per the FDA 510(k) summary for K152300, the indications for use for this device are the same as those for its predicate device (K113853). We agree with the applicant that Command Center maps to the same MS-DRG as existing technologies. As a result, we believe that Command Center is substantially similar to existing technologies because it uses the same or similar mechanism of action, maps to the same MS-DRG, and involves the treatment of the same or similar type of disease and patient population when compared to existing technologies, including its predicate device (K113853). We note that, per our policy, if technologies are substantially similar to each other, we use the earliest market availability date as the beginning of the newness period for the technologies. Accordingly, if we determine that Command Center is substantially similar to existing glycemic management systems as described previously, because they all were FDA market authorized prior to Command Center, the newness period for Command Center would have commenced even earlier than its FDA

clearance date in 2017. We are inviting public comments on our proposal to disapprove new technology add-on payments for Command Center, including whether the technology is substantially similar to existing technologies and whether it meets the newness criterion.

#### Cost Criterion

Regarding the cost criterion, we note the following concerns with the cost analysis provided by the applicant. We note that the applicant did not remove any charges or indirect charges for prior technology. We are interested in additional information regarding whether Command Center would replace any prior technology, such as existing electronic glycemic management tools. We also note that the average standardized charges per case were not calculated according to the instructions in Appendix A—Standardizing Charges.<sup>38</sup> Instead, the applicant calculated a single standardization rate factor (1.71) across all hospitals included in the analysis and multiplied it by the average charge per case (unstandardized with no case weight) for every MS-DRG in the analysis. In addition, we note that the final inflated case-weighted standardized charge per case was not provided. As such, we are unable to determine whether the final inflated case weighted standardized charge per case exceeds the case weighted threshold amount; that is, whether Command Center meets the cost criterion for new technology add-on payment. We are inviting public comments on whether Command Center meets the cost criterion.

#### Substantial Clinical Improvement Criterion

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Command Center.

After reviewing the information provided by the applicant, we have the following concerns regarding whether Command Center meets the substantial clinical improvement criterion. We note that it appears that the applicant submitted studies using its predicate device (K113853) to support its assertions as to why Command Center represents a substantial clinical

improvement. However, the applicant did not present any clinical data comparing Command Center to its predicate device. With respect to the applicant's claims that Command Center offers a treatment option for patients unresponsive to, or ineligible for, currently available treatments, we note that the applicant compared its predicate device to paper-based insulin infusion protocol,<sup>39</sup> intensive glucose control,<sup>42</sup> and provider-managed insulin therapy<sup>43</sup> on achieving target blood glucose timelier, improving clinical outcomes, and reducing resource use. However, we did not receive any information that identifies a patient population that is unresponsive to or ineligible for other available electronic glycemic management solutions, such as the GlucoStabilizer Insulin Dosing Calculator 3.0, the EndoTool™ Drug Dose Calculator, the EndoTool SubQ™, the EndoTool IV 1.10, and its own predicate device, and for which Command Center could be used.

With respect to the assertion that Command Center offers the ability to diagnose a medical condition where it is currently undetectable or earlier than allowed by currently available methods, and that the use of Command Center to make a diagnosis affects the management of the patient, the applicant provided a study showing that patients who relied on the predicate 2012 Glucomanometer™ device were more likely than those on standard

<sup>39</sup> Mumpower, A; et al Glycemic Control Using eGMS and Readmission Rates in Cardiovascular Patients Hospitalized with AMI, CHF or Undergoing CABG During a System-Wide Glycemic Initiative. Annual Diabetes Technology Meeting. November 2016. Study was unpublished but presented at a national meeting poster session.

<sup>40</sup> Ponnusamy D, Piziali V, Patel S, Urbanosky R. B2-3: Comparative Effectiveness of a Computerized Algorithm versus a Physician Instituted Protocol to Manage Insulin Infusions after Cardiac Surgery. *Clin Med Res.* 2014 Sep;12(1-2):97. doi: 10.3121/cmr.2014.1250.b2-3. PMID: PMC4453383.

<sup>41</sup> Smiley, D; Cardona, S; Weaver, J; Register, K; Peng, L; Pasquel, F; Umpierrez, G. (Emory University) Hospitalization Costs, Resource Utilization, and Clinical Outcome in Patients Undergoing CABG Receiving Intensive Versus Conservative Glucose Control. American Diabetes Association Scientific Sessions. June 2014.

<sup>42</sup> Umpierrez G, Cardona S, Pasquel F, et al. Randomized Controlled Trial of Intensive Versus Conservative Glucose Control in Patients Undergoing Coronary Artery Bypass Graft Surgery: GLUCO-CABG Trial. *Diabetes Care.* 2015 Sep;38(9):1665-72. doi: 10.2337/dc15-0303. Epub 2015 Jul 15. PMID: 26180108; PMID: PMC4542267.

<sup>43</sup> Aloji J, Bode BW, Ullal J, et al. Comparison of an Electronic Glycemic Management System Versus Provider-Managed Subcutaneous Basal Bolus Insulin Therapy in the Hospital Setting. *J Diabetes Sci Technol.* 2017 Jan;11(1):12-16. doi: 10.1177/1932296816664746. Epub 2016 Sep 25. PMID: 27555601; PMID: PMC5375075.

<sup>36</sup> FDA, June 14, 2006, K053137 EndoTool™ Drug Dose Calculator (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K053137>, accessed 1/2/2026).

<sup>37</sup> FDA, April 24, 2015, K142918 EndoTool SubQ™ (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K142918>, accessed 1/2/2026).

<sup>38</sup> Medicare Electronic Application Request Information System (MEARIS™). Resources: NTAP Appendix A Standardizing Charges (<https://mearis.cms.gov/public/resources>, accessed 1/8/2026).

treatments to reach target blood glucose range.<sup>44</sup> However, reaching target blood glucose is not a diagnosis, and therefore does not identify and provide evidence for a specific medical condition in a population in which the condition is currently undetectable that can be diagnosed by Command Center, nor how Command Center can diagnose a medical condition earlier than currently available technologies, such as other electronic glycemic management solutions. Furthermore, the FDA 510(k) clearance covering Command Center states that it is not a substitute for, but rather an adjunct to clinical reasoning and that no medical decision should be based solely on the recommended guidance provided by this software program. We further note that the study did not indicate whether the difference between the two groups of patients was statistically significant.

Similarly, with regard to the applicant's assertion that Command Center significantly improves clinical outcomes for a patient population compared to currently available treatments, we note that one of the two pieces of evidence provided by the applicant mentioned the features and functionalities of Command Center, like real-time glycemic insights, benchmarking, predictive analytics, and system-wide supporting.<sup>45</sup> However, we did not receive any evidence that compared the clinical outcomes

between Command Center and those of other existing technologies. The supporting evidence for these claims included study results on the clinical<sup>46</sup> and financial<sup>47</sup> effects of glucose control in general, and the effects of electronic glycemic management systems on hypoglycemia.<sup>48</sup> Although the applicant claimed that its software has been recognized repeatedly in the community for its advanced,<sup>49 50</sup> innovative approach and contribution to medical care, this does not correspond with a clinical outcome under § 412.87(b)(1)(ii)(C). As a result, we are unable to determine whether Command Center significantly improves clinical outcomes relative to existing treatments.

After review of the information provided by the applicant, we are unable to determine that Command Center represents a substantial clinical improvement over existing technologies, and therefore, we are proposing to disapprove new technology add-on payments for Command Center for FY 2027.

We are inviting public comments on whether Command Center meets the substantial clinical improvement criterion and our proposal to disapprove new technology add-on payments for Command Center for FY 2027.

#### c. GAMIFANT® (emapalumab-lzsg)

Sobi, Inc. submitted an FY 2027 application for new technology add-on

payments for GAMIFANT®. According to the applicant, GAMIFANT® is an interferon gamma (IFN $\gamma$ )-blocking antibody that targets and neutralizes IFN $\gamma$  to stop the hyperinflammatory feedback loop of macrophage activation syndrome (MAS). Per the applicant, GAMIFANT® is an intravenous infusion consisting of a 6 mg/kg loading dose or a 3 mg/kg treatment dose administered over 1 hour. The applicant stated that in the GAMIFANT® studies, adults received 10 infusions (1 loading dose of 6 mg/kg and 9 treatment doses of 3 mg/kg) over a median 29 days in the inpatient setting. We note that the applicant is seeking new technology add-on payments for GAMIFANT® for its indication for the treatment of adult and pediatric (newborn and older) patients with hemophagocytic lymphohistiocytosis (HLH)/MAS in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.<sup>51</sup>

The following table provides an overview of the new technology add-on payment application for GAMIFANT® and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP250926GGG85>.

**BILLING CODE 4120-01-P**

<sup>44</sup> Mabrey M, Ullal J, McFarland R, et al. eGlycemic Management Solution Safely Achieves Prescribed Glycemic Target with a Low Incidence of Hypoglycemia in Patients with Acute Myocardial Infarction in the Hospital. American Association of Clinical Endocrinologists Scientific & Clinical Congress. May 2015.

<sup>45</sup> Healthcare Tech Outlook. "Glytec Modernizing Inpatient Insulin Management." (Glytec | Top Diabetes Management Platform-2025.) <https://www.healthcaretechoutlook.com/glytec>. Accessed 12/12/2025.

<sup>46</sup> Mumpower (2016). *op.cit.*

<sup>47</sup> Smiley (2014). *Op.cit.*

<sup>48</sup> Rabinovich (2018). *Op.cit.*

<sup>49</sup> Healthcare Tech Outlook. *Op.cit.*

<sup>50</sup> Glytec. "Glytec Honored as Gold Stevie® Award Winner in 2025 Stevie® Awards for Technology Excellence—Glytec." <https://glytec.com/newsroom/glytec-honored-as-gold-stevie-award-winner-in-2025-stevie-awards-for-technology-excellence/>. July 29, 2025. Accessed 1/13/2026.

<sup>51</sup> In 2018, FDA granted GAMIFANT® approval under a BLA application for the treatment of adult and pediatric (newborn and older) patients with primary HLH with refractory, recurrent, or progressive disease or intolerance with conventional therapy.

|                                                   |                               | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Preliminary CMS Assessment                        |
|---------------------------------------------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Unique ICD-10-PCS code(s)</b>                  |                               | XW033MA and XW043MA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | No concerns.                                      |
| <b>Newness Criterion</b>                          | <b>Newness Period</b>         | sBLA on June 27, 2025, for the treatment of adult and pediatric (newborn and older) patients with HLH/ MAS in known or suspected Still's disease, including systemic sJIA, with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Newness date: June 27, 2025.                      |
|                                                   | <b>Substantial Similarity</b> | Uses a new mechanism of action.<br>Maps to a new MS-DRG.<br>Treats a new disease and/or a new patient population.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Not substantially similar to existing treatments. |
| <b>Cost Criterion</b>                             |                               | Scenario 1: 143 claims mapping to 13 MS-DRGs, with none exceeding more than 8% of the total identified claims.<br><br>Scenario 2: 22 claims mapping to 2 MS-DRGs, with 50% of claims mapping to each MS-DRG 516 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC) and MS-DRG 545 (Connective Tissue Disorders with MCC).<br><br>Scenario 3: 308 claims mapping to 22 MS-DRGs, with none exceeding more than 4% of the total identified claims per year.<br><br>Scenario 4: 66 claims mapping to 4 MS-DRGs, with none exceeding more than 17% of the total identified claims per year.<br><br>Final inflated average case-weighted standardized charge per case (Scenario 1 – \$5,979,504; Scenario 2 – \$5,956,537; Scenario 3 – \$5,984,804; Scenario 4 – \$5,956,716) exceeded the average case-weighted threshold amount (Scenario 1 – \$111,457; Scenario 2 – \$87,773; Scenario 3 – \$104,117; Scenario 4 – \$93,390). | Meets cost criterion.                             |
| <b>Substantial Clinical Improvement Criterion</b> |                               | Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments.<br><br>Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.<br><br>Provided 1 published study and 6 unpublished references assessing the technology, 2 practice guidelines, and other information.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | See following discussion.                         |

## ICD-10 Coding

After review of the information provided by the applicant, we believe the relevant ICD-10-CM diagnosis

codes to identify the indication of the treatment of adult and pediatric (newborn and older) patients with HLH/ MAS in known or suspected Still's

disease, including sJIA, with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS are:

| ICD-10-CM code | Description                                                              |
|----------------|--------------------------------------------------------------------------|
| M06.10         | Adult-onset Still's disease                                              |
| M08.211        | Juvenile rheumatoid arthritis with systemic onset, right shoulder        |
| M08.212        | Juvenile rheumatoid arthritis with systemic onset, left shoulder         |
| M08.221        | Juvenile rheumatoid arthritis with systemic onset, right elbow           |
| M08.222        | Juvenile rheumatoid arthritis with systemic onset, left elbow            |
| M08.231        | Juvenile rheumatoid arthritis with systemic onset, right wrist           |
| M08.232        | Juvenile rheumatoid arthritis with systemic onset, left wrist            |
| M08.241        | Juvenile rheumatoid arthritis with systemic onset, right hand            |
| M08.242        | Juvenile rheumatoid arthritis with systemic onset, left hand             |
| M08.251        | Juvenile rheumatoid arthritis with systemic onset, right hip             |
| M08.252        | Juvenile rheumatoid arthritis with systemic onset, left hip              |
| M08.261        | Juvenile rheumatoid arthritis with systemic onset, right knee            |
| M08.262        | Juvenile rheumatoid arthritis with systemic onset, left knee             |
| M08.271        | Juvenile rheumatoid arthritis with systemic onset, right ankle and foot  |
| M08.272        | Juvenile rheumatoid arthritis with systemic onset, left ankle and foot   |
| M08.28         | Juvenile rheumatoid arthritis with systemic onset, vertebrae.            |
| M08.29         | Juvenile rheumatoid arthritis with systemic onset, multiple sites.       |
| M08.2A         | Juvenile rheumatoid arthritis with systemic onset, other specified site. |

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We are inviting public comments on the use of these ICD-10-CM diagnosis codes to identify this indication for purposes of the new technology add-on payment, if approved.

**Newness Criterion**

Regarding substantial similarity, based on the information available at the time of this proposed rule, we agree with the applicant that GAMIFANT® has a new mechanism of action and treats a new type of disease or patient population compared to existing technology, because it is the only FDA-approved treatment for HLH/MAS in known or suspected Still's disease. We note that the applicant did not provide an explanation for why GAMIFANT® would not map to the same MS-DRGs as other therapies for HLH/MAS in Still's disease. Therefore, based on information available at the time of this proposed rule, we believe that GAMIFANT® is not substantially similar to existing technology and meets the newness criterion. We consider the beginning of the newness period to commence on June 27, 2025, the date on which GAMIFANT® received FDA market authorization for this indication.

We are inviting public comments on whether GAMIFANT® is substantially similar to existing technologies and whether GAMIFANT® meets the newness criterion.

**Cost Criterion**

Regarding the cost criterion, we agree with the applicant that the technology meets the cost criterion. We are inviting public comments on whether GAMIFANT® meets the cost criterion.

**Substantial Clinical Improvement Criterion**

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for GAMIFANT®.

After review of the information provided by the applicant, we have the following concerns regarding whether GAMIFANT® meets the substantial clinical improvement criterion. The applicant asserted GAMIFANT® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments since GAMIFANT® is the first and only FDA-approved treatment for HLH/MAS in known or suspected Still's disease with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS. However, we question whether GAMIFANT® offers a treatment option for patients unresponsive to, or ineligible for, currently available treatments, because several second- and third-line therapies, including cyclosporine, etoposide, anakinra, and intravenous immunoglobulin, can also treat patients with an inadequate response or intolerance to glucocorticoids or with recurrent MAS.<sup>52 53 54 55</sup>

<sup>52</sup> Shakoory B, et al. The 2022 EULAR/ACR points to consider at the early stages of diagnosis and management of suspected haemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS). *Ann Rheum Dis*. 2023;82(10):1271–1285.

<sup>53</sup> Hines MR, et al. Consensus-based guidelines for the recognition, diagnosis, and management of hemophagocytic lymphohistiocytosis in critically

ill children and adults. *Crit Care Med*. 2022;50(5):860–872.

Furthermore, we are unable to assess the applicant's assertion that GAMIFANT® significantly improves clinical outcomes relative to other available services or technologies without a comparison of outcomes to other therapies for patients with an inadequate response or intolerance to glucocorticoids or with recurrent MAS. In addition, while the applicant stated that GAMIFANT® achieves substantially improved clinical outcomes with a clear and positive benefit:risk profile in treating HLH/MAS patients who had an inadequate response to glucocorticoids and that GAMIFANT® initiation results in a clinically meaningful reduction of glucocorticoid dosing and contributes to the positive benefit:risk profile for the treatment of patients with HLH/MAS, we question whether having a positive benefit:risk profile is a relevant outcome under § 412.87(b)(1)(ii)(C) because it does not address how GAMIFANT® improves clinical outcomes relative to other therapies that may be used to treat HLH/MAS patients who had an inadequate response to glucocorticoids or with recurrent MAS.

We also note that to support its assertion regarding improved clinical outcomes, the applicant provided results from two clinical studies, NI-0501-06 and NI-0501-14. We note that all patients in the studies responded inadequately to high-dose

ill children and adults. *Crit Care Med*. 2022;50(5):860–872.

<sup>54</sup> Baldo F, et al. Current treatment in MAS worldwide: a systematic literature review to inform the METAPHOR project. *Rheumatology* (Oxford). 2025, 64, 32–44.

<sup>55</sup> Minoia F, et al. Clinical features, treatment, and outcome of macrophage activation syndrome complicating systemic juvenile idiopathic arthritis, a multinational, multicenter study of 362 patients. *Arthritis Rheumatol*. 2014;81(2):112–117.

glucocorticoids prior to study treatment, and providers would typically initiate other second- and third-line therapies in this patient population. While the applicant claimed GAMIFANT® reduces glucocorticoid dosing, it is unclear whether GAMIFANT® significantly reduces glucocorticoid dosing compared to other therapies that may be used in these patients. In addition, some therapies used for MAS in Still's disease such as anakinra and cyclosporine were allowed during these studies and could have affected the outcomes, and thus, we are unclear how these studies support the assertion of improved outcomes relative to other available treatments.

While the applicant claims a positive benefit:risk profile for GAMIFANT®, the submitted clinical information does not clearly explain how it was determined whether serious adverse events were related to GAMIFANT®, nor does it provide sufficient detail on the reported serious adverse events. Specifically, we note that while De Benedetti et al. (2023) states that there were 9 serious adverse events in NI-0501-06 and the long-term follow-up, which appear to include one cytomegalovirus reactivation, one SJA flare, one edema

of the ankle, one MAS episode, one cardiopulmonary failure, and one severe neutropenia, it is unclear what the other three reactions were and which were related to GAMIFANT®. Grom et al. (2025) also stated there were 7 serious adverse events in NI-0501-14, but it is unclear what these events were and which were related to GAMIFANT®.

Furthermore, we would appreciate more detail on the visual analogue scale (VAS) scoring system used in the clinical trials in order to fully assess the efficacy outcome data. We also note that the long-term clinical trials included up to 12 months of follow-up, and we question if this is enough time to assess for MAS recurrence.

After review of the information provided by the applicant, we are unable to determine whether GAMIFANT® represents a substantial clinical improvement over existing technologies, and therefore, we are proposing to disapprove new technology add-on payments for GAMIFANT® for FY 2027.

We are inviting public comments on whether GAMIFANT® meets the substantial clinical improvement criterion and our proposal to disapprove FY 2027 new technology add-on payments for GAMIFANT®.

#### d. Orca-T

Orca Bio submitted an FY 2027 application for new technology add-on payments for Orca-T. According to the applicant, Orca-T is an allogeneic stem cell and T-cell immunotherapy derived from a human leukocyte antigen (HLA)-matched donor for the curative treatment of hematologic malignancies, including acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), high-risk myelodysplastic syndrome (MDS), and mixed-phenotype acute leukemia (MPAL), in adults. Orca-T is administered as four single-dose, patient-specific infusions composed of purified hematopoietic stem and progenitor cells (HSPC), regulatory T cells (Treg), and conventional T cells (Tcon) along with a diluent from an HLA-matched donor blood apheresis product.

The following table provides an overview of the new technology add-on payment application for Orca-T and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251003TH4EH>.

|                                                   |                               | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                | Preliminary CMS Assessment           |
|---------------------------------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| <b>Unique ICD-10-PCS code(s)</b>                  |                               | XW033BA and XW043BA                                                                                                                                                                                                                                                                                                                                                                                                                 | No concerns.                         |
| <b>Newness Criterion</b>                          | <b>Newness Period</b>         | FDA decision anticipated by May 1, 2026.                                                                                                                                                                                                                                                                                                                                                                                            | Pending FDA marketing authorization. |
|                                                   |                               | No commercial delay expected.                                                                                                                                                                                                                                                                                                                                                                                                       |                                      |
|                                                   | <b>Substantial Similarity</b> | Uses a new mechanism of action.<br>Maps to a new MS-DRG.<br>Treats the same disease and the same patient population.                                                                                                                                                                                                                                                                                                                | See following discussion.            |
| <b>Cost Criterion</b>                             |                               | Scenario 1: 454 claims mapping to MS-DRG 014 (Allogeneic Bone Marrow Transplant).<br>Scenario 2: 2,033 claims mapping to 16 MS-DRGs, with 51% mapping to MD-DRG 834 (Acute Leukemia with MCC).<br>Final inflated average case-weighted standardized charge per case (Scenario 1 – \$2,543,171; Scenario 2 – \$2,444,500) exceeded the average case-weighted threshold amount (Scenarios 1 and 2 – \$1,885,660).                     | Meets cost criterion.                |
| <b>Substantial Clinical Improvement Criterion</b> |                               | Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments.<br>Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.<br>Provided 3 published and 9 unpublished studies assessing the technology, 4 published studies assessing comparator technologies, and other information. | See following discussion.            |

### Newness Criterion

Regarding substantial similarity, the applicant stated that Orca-T does not have the same or similar mechanism of action as any therapies that are currently used in potentially curative hematologic malignancy treatments mapped to Pre-MDC MS-DRG 018 (Chimeric Antigen Receptor [CAR] T-cell and Other Immunotherapies). While the applicant asserted that Orca-T's engineered product is novel in composition of HSPC, Treg, and Tcon fractions derived from an allograft and administered in a specific sequence, we note that the cell lines isolated in Orca-T already exist in an unmanipulated allograft administered as part of an allogeneic hematopoietic stem cell transplantation (alloHSCT) after cytoreductive conditioning. However, we agree with the applicant that Orca-T is not substantially similar to alloHSCT because it maps to a different MS-DRG than alloHSCTs, which are mapped to Pre-Major Diagnostic Category (MDC) MS-DRG 014 (Allogeneic Bone Marrow Transplant). Therefore, based on information available at the time of this proposed rule, we believe that Orca-T is not substantially similar to existing technologies and meets the newness criterion. We are inviting public comments on whether Orca-T is substantially similar to existing technologies and whether Orca-T meets the newness criterion.

### Cost Criterion

Regarding the cost criterion, we agree with the applicant that the technology meets the cost criterion. We are inviting public comments on whether Orca-T meets the cost criterion.

### Substantial Clinical Improvement Criterion

Regarding substantial clinical improvement, we received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Orca-T, which we are summarizing in this section.

*Comment:* A commenter submitted a public comment regarding whether Orca-T meets the substantial clinical improvement criterion, stating that CMS should prioritize measurable, reproducible, and auditable clinical improvement rather than narrative claims alone in assessing substantial clinical improvement. The commenter stated that, where possible, substantial clinical improvement determinations

should be supported by standardized episode definitions, clearly described patient selection and comparators, and outcome measures, such as complications, length of stay, and readmissions, that can be independently reproduced across sites. In addition, the commenter emphasized that it may be especially important that claimed improvements are supported by reproducible episode definitions, clearly documented eligibility and protocol criteria, and integrity-preserving audit trails that can be independently reviewed when decision support (including AI-assisted decision support) is used for patient selection. The commenter also recommended that CMS give greater weight to submissions that provide traceable evidence linkage from claimed improvements back to underlying data and protocol definitions to improve consistency and transparency. The commenter suggested that this would help ensure that new technology add-on payments recognize technologies delivering clinically meaningful and verifiable improvements in real-world inpatient care.

*Response:* We thank the commenter for the comment. After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether Orca-T meets the substantial clinical improvement criterion.

We are concerned about the lack of technology-specific evidence in support of the applicant's assertion that Orca-T provides a treatment option for patients unresponsive to, or ineligible for, currently available treatments. The applicant claimed that Orca-T is favorable to patients at risk of severe toxicities and mortality with standard of care (SoC) alloHSCT. We note that the supporting evidence for this claim is comprised of background literature about the impact of graft-versus-host disease (GVHD) on patients with hematologic malignancies in general, but does not identify a patient population that is unresponsive to, or ineligible for, alloHSCT, nor does it demonstrate that Orca-T can treat such a patient population. We remain unclear if there is a group of patients who can be treated with Orca-T, but cannot receive existing treatments for hematologic malignancies such as alloHSCT, CAR T-cell therapies, and chemotherapies.

We are also concerned that we are unable to assess whether Orca-T significantly improves clinical outcomes relative to services or technologies

previously available without evidence comparing outcomes for Orca-T to other therapies available for patients with hematologic malignancies, including CAR T-cell therapies. While the evidence compared Orca-T to conventional MAC-alloHSCT approaches using standard GVHD prophylaxis regimens, it did not include comparisons to other therapeutic modalities such as CAR-T cell therapies which are available for the treatment of patients with hematologic malignancies and may not be associated with the risk of GVHD. We also note that the supporting evidence for this claim does not include comparisons to other treatment options used in this patient population outside the unmanipulated allo-HSCT setting, such as chemotherapies, nor does it compare the effects of Orca-T with reduced-toxicity or reduced-intensity conditioning on regimen-related toxicity and other clinical outcomes. As a result, we question whether Orca-T results in improved clinical outcomes relative to existing hematologic malignancy treatments.

We are inviting public comments on whether Orca-T meets the substantial clinical improvement criterion.

### e. RAPIBLYK™ (landiolol)

AOP Health US LLC submitted a FY 2027 application for new technology add-on payments for RAPIBLYK™. According to the applicant, RAPIBLYK™ is a beta-1 (β1) adrenergic blocker that inhibits adrenaline and noradrenaline's effects on the heart for short-term reduction of ventricular rate in adults with supraventricular tachycardia (SVT), including atrial fibrillation (AF) and atrial flutter (AFL). RAPIBLYK™ is supplied as a 280 mg lyophilized powder in a single-dose vial (equivalent to 300 mg of landiolol HCl) and, following reconstitution, is administered as a continuous intravenous infusion titrated according to ventricular rate.<sup>56</sup> The applicant stated that during an inpatient stay, the average patient requires five RAPIBLYK™ vials.

The following table provides an overview of the new technology add-on payment application for RAPIBLYK™ and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251006EVR3D>.

<sup>56</sup> AOP Orphan Pharmaceuticals. (2024, November). RAPIBLYK (landiolol) for injection, for intravenous use: highlights of prescribing information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/217202s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217202s000lbl.pdf).

|                                                   |                               | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                     | Preliminary CMS Assessment |
|---------------------------------------------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| <b>Unique ICD-10-PCS code(s)</b>                  |                               | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                       | No concerns.               |
| <b>Newness Criterion</b>                          | <b>Newness Period</b>         | NDA approval on November 22, 2024, for the short-term reduction of ventricular rate in adults with SVT including AF and AFL.<br><br>Commercial availability delay to July 21, 2025.                                                                                                                                                                                                                                      | See following discussion.  |
|                                                   | <b>Substantial Similarity</b> | Uses a new mechanism of action.<br><br>Treats a new disease and/or a new patient population.                                                                                                                                                                                                                                                                                                                             | See following discussion.  |
| <b>Cost Criterion</b>                             |                               | 53,447 claims mapping to 577 MS-DRGs, with none exceeding more than 10% of the total identified claims.<br><br>Final inflated average case-weighted standardized charge per case (\$108,394) exceeded the average case-weighted threshold amount (\$84,401).                                                                                                                                                             | Meets cost criterion.      |
| <b>Substantial Clinical Improvement Criterion</b> |                               | Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments.<br><br>Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.<br><br>Provided 3 published studies assessing the technology. 1 published study assessing comparator technology, and 1 practice guideline. | See following discussion.  |

#### Newness Criterion

Regarding commercial availability, the applicant stated that, after its NDA approval on November 22, 2024, RAPIBLYK™ was not immediately for sale and became commercially available on July 21, 2025, because the applicant needed to work through a number of time-intensive steps to facilitate U.S. commercial launch, including establishing a new entity for U.S. operations, identifying and contracting with a third-party logistics vendor and distributor, and identifying and contracting with wholesalers and group purchasing organizations. We are interested in additional information regarding the cause of the delay in commercial availability.

Regarding substantial similarity, we disagree with the applicant that RAPIBLYK™ uses a different mechanism of action compared to existing heart rate control technologies. Per the applicant, RAPIBLYK™ directly blocks  $\beta_1$ -adrenergic receptors on cardiac myocytes preventing catecholamine-induced increases in heart rate and conduction velocity. According to the applicant, unlike traditional beta blockers that rely on hepatic metabolism, have 3- to 12-hour half-lives, and exhibit lower  $\beta_1/\beta_2$  selectivity ratios, RAPIBLYK™ is rapidly hydrolyzed by tissue and plasma esterases, yielding an ultra-short half-life of approximately 3 to 4 minutes without requiring hepatic clearance, and demonstrates an exceptionally high  $\beta_1/$

$\beta_2$  selectivity ratio. While we recognize that RAPIBLYK™ is metabolized and cleared differently compared to other beta blockers, we do not believe that this constitutes a unique mechanism of action because RAPIBLYK™, like other beta blockers, blocks  $\beta_1$ -adrenergic receptors, reducing sympathetic stimulation.

Additionally, we disagree with the applicant that RAPIBLYK™ treats a new patient population or disease compared to existing technology because there are other beta blockers, such as esmolol, that are FDA-approved for the treatment of adults with SVT, including AF and AFL. According to the applicant, RAPIBLYK™ is uniquely suited to resolve acute AF in a patient population with impaired cardiac function and hemodynamic instability and hypotension. However, we note that other therapies, such as esmolol, can also be used to treat acute AF patients with impaired cardiac function. While the applicant stated that in RAPIBLYK™'s prescribing label, a dosing regimen is included for patients with impaired cardiac function, we note that the absence of a dosing regimen for cardiac impairment in the prescribing label<sup>57</sup> for esmolol does not preclude

<sup>57</sup> WG Critical Care, LLC. (1986, December). *Esmolol hydrochloride in water for injection, for intravenous use: highlights of prescribing information*. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/205703s0031b1.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/205703s0031b1.pdf).

the use of this drug in this patient population. Furthermore, in regards to the applicant's claim that RAPIBLYK™ can be used in acute AF patients with hemodynamic instability, we note that according to both prescribing labels, esmolol and RAPIBLYK™ have the same contraindications for use in patients with hemodynamic instability, including those with severe sinus bradycardia, heart block greater than first degree, sick sinus syndrome, decompensated heart failure, and cardiogenic shock. While the applicant made several statements related to RAPIBLYK™'s dosing regimen, safety profile, and suitability for cardiac impaired patients, we believe this is relevant to the assessment of substantial clinical improvement, rather than of newness. We did not receive evidence identifying a new patient population or type of disease which RAPIBLYK™ treats that cannot be treated with existing technologies such as esmolol, amiodarone, or digoxin.

Accordingly, as it appears that RAPIBLYK™ and esmolol may use the same or similar mechanism of action to achieve a therapeutic outcome, are assigned to the same MS-DRG, and treat the same or similar patient population and disease, that is, adult patients with SVT including AF and AFL, we believe that these technologies are substantially similar to each other.

We note that, per our policy, if technologies are substantially similar to each other, we use the earliest market availability date as the beginning of the

newness period for the technologies. Accordingly, if we determine that RAPIBLYK™ is substantially similar to esmolol, we believe the newness period for RAPIBLYK™ would begin on December 31, 1986, the date esmolol received FDA approval. Since esmolol has been on the U.S. market since 1986, the 3-year anniversary date of its entry onto the market occurred prior to FY 2027. Therefore, RAPIBLYK™ would not be considered new and would be ineligible for new technology add-on payments for FY 2027.

We are inviting public comments on whether RAPIBLYK™ is substantially similar to existing technologies and whether RAPIBLYK™ meets the newness criterion.

#### Cost Criterion

Regarding the cost criterion, we agree with the applicant that the technology meets the cost criterion. We are inviting public comments on whether RAPIBLYK™ meets the cost criterion.

#### Substantial Clinical Improvement Criterion

Regarding substantial clinical improvement, we also received a few public comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for RAPIBLYK™, which we are summarizing in this section.

*Comment:* The applicant submitted a comment in response to the New Technology Town Hall meeting. With regard to a question on which high-risk population with AF is not well-managed by other beta blockers, the applicant stated that, based on Koukoulitsios et al. (2025) and the 2023 AF Consensus Guidelines, this refers to patients with impaired cardiac output, specifically those with an ejection fraction below 40 percent, as described in its application.<sup>58 59</sup> The applicant also submitted one study in addition to its comment letter while discussing two other studies to support RAPIBLYK™<sup>±s</sup>

substantial clinical improvement.<sup>60 61 62</sup> The applicant submitted Dizdarevic et al. (2025), a multicenter, prospective observational study of 450 European patients with SVTs, including AF and AFL, requiring acute rate control treated with RAPIBLYK™ across intensive care units (ICUs), emergency departments, and general wards to support its claim that RAPIBLYK™ provides a new, effective heart rate control option for acute AF patients with significant comorbidities, including chronic heart failure (CHF) and renal impairment. Per the applicant, the authors defined subgroups by arrhythmia type, comorbidities (such as sepsis or acute myocardial infarction), and concomitant interventions. According to the applicant, the primary endpoints included RAPIBLYK™ utilization patterns, such as infusion duration, dosing, and the route of administration (central or peripheral venous access). The applicant stated that the secondary endpoints included time to heart rate control, sinus rhythm restoration, need for cardioversion, blood pressure effects, ICU and hospital length of stay (LOS), and safety outcomes, such as adverse events (AEs), serious AEs (SAEs), and major adverse cardiovascular events (MACEs). As reported by the applicant, Dizdarevic et al. (2025) showed that 74.2 percent of patients receiving RAPIBLYK™ achieved heart rate control within 4 hours of discontinuation. Per the applicant, the median heart rate at the end of RAPIBLYK™ infusion was 100 beats per minute (bpm), with statistically significant reductions compared to baseline ( $p < 0.001$ ) across all arrhythmia subgroups. The applicant also stated that patients' blood pressure

generally remained stable throughout treatment, with no clinically meaningful changes in systolic or diastolic values, and that study showed favorable safety outcomes: AEs occurred in 17.6 percent of patients, but only 2.0 percent experienced hypotension and only 1 case reported bradycardia. Per the applicant, none of the AEs or MACEs were attributed to RAPIBLYK™ treatment, and only 6 patients (1.3 percent) discontinued therapy due to AEs.

The applicant also discussed a review article that was already submitted (Floria et al., 2024) to support its claims that RAPIBLYK™ is effective in reducing the incidence of postoperative atrial fibrillation (POAF) in cardiac surgery patients. According to the applicant, this review provided a comprehensive overview of RAPIBLYK™, including its pharmacology, clinical applications, efficacy, safety profile, and future directions in research and clinical data. Per the applicant, as described in Floria et al. (2024),<sup>33</sup> in the randomized, double-blind, placebo-controlled PASCAL trial, coronary artery bypass grafting (CABG) patients who received RAPIBLYK™ infusion had AF incidence of 5 percent compared to 34.3 percent for placebo ( $p = 0.0006$ ), along with reductions in inflammatory and ischemic biomarkers. Per the applicant, similarly, the PLATON study of 60 patients with left ventricular ejection fraction below 35 percent who had cardiac surgery performed with cardiopulmonary bypass found AF in only 10 percent of the RAPIBLYK™ group compared to 40 percent of controls ( $p = 0.002$ ), along with improved brain natriuretic peptide levels, ischemic biomarkers, and shorter hospital stays. According to the applicant, across these trials, inclusion criteria focused on patients undergoing major cardiac surgery, with some studies targeting elderly populations or those with reduced ventricular function, while exclusion criteria involved contraindications to beta blockers, such as severe bradycardia or advanced heart block. The applicant stated that endpoints consistently measured AF incidence, biomarker changes, and safety outcomes. Per the applicant, results were statistically significant, confirming that RAPIBLYK™ not only reduces POAF but also improves perioperative biomarker profiles and clinical outcomes. The applicant stated that its rapid onset, short half-life, and high cardioselectivity make RAPIBLYK™ a safe and effective option for perioperative heart rate control,

<sup>58</sup> Koukoulitsios G, Tsikritsaki K, Magklaras G, Koutivas AM, Kalogeromitros A, Papaioannou V. Comparison of Landiolol and Esmolol on Haemodynamic Responses During Weaning of Intensive Care Unit Patients with Reduced Ejection Fraction after Vascular Surgery. *Card Fail Rev*. 2025 May 21;11:e13. <https://doi.org/10.15420/cfr.2024.18>.

<sup>59</sup> Cafaro T, Allwood M, McIntyre WF, Park LJ, Daza J, Ofori SN, Ke Wang M, Borges FK, Conen D, Marcucci M, Healey JS, Whitlock RP, Lamy A, Belley-Côté EP, Spence JD, McGillion M, Devereaux PJ. Landiolol for the prevention of postoperative atrial fibrillation after cardiac surgery: a systematic review and meta-analysis. *Can J Anaesth*. 2023 Nov;70(11):1828–1838. <https://doi.org/10.1007/s12630-023-02586-0>.

<sup>60</sup> Dizdarevic, A.-M., Šramko, M., Mangner, N., Merkely, B., Zima, E., Nikolaos, N., Scherr, D., Knotzer, J., Köglberger, P., Nouvaki, Z., Martinek, M., Hnat, T., Bethlehem, C., Frás, Z., Goździk, W., Kotanidou, A., Dąbrowski, W., Lesiak, M., Stefanska-Wronka, K., . . . Siller-Matula, J. (2025). A multicentre observational study on landiolol use, efficacy, and safety in European patients with supraventricular arrhythmia (Landi-UP). *European Heart Journal: Acute Cardiovascular Care*. Advance online publication. <https://doi.org/10.1093/ehjacc/zuaf129>.

<sup>61</sup> Floria, M., Oancea, A. F., Morariu, P. C., Burlacu, A., Iov, D. E., Chiriac, C. P., Baroi, G. L., Stafie, C. S., Cuciureanu, M., Scripcariu, V., & Tanase, D. M. (2024). An overview of the pharmacokinetics and pharmacodynamics of landiolol (an ultra-short acting  $\beta_1$  selective antagonist) in atrial fibrillation. *Pharmaceutics*, 16(4), 517. <https://doi.org/10.3390/pharmaceutics16040517>.

<sup>62</sup> Perrett, M., Gohil, N., Tica, O., Bunting, K. V., & Kotecha, D. (2024). Efficacy and safety of intravenous beta-blockers in acute atrial fibrillation and flutter is dependent on beta-1 selectivity: A systematic review and meta-analysis of randomised trials. *Clinical Research in Cardiology*, 113(6), 831–841. <https://doi.org/10.1007/s00392-023-02295-0>.



particularly in critically ill patients or those with compromised cardiac function. According to the applicant, these trials also show improved outcomes beyond rhythm control, including reductions in inflammatory and ischemic biomarkers, shorter hospital stays, and better tolerance in compromised cardiac patients. The applicant stated that, taken together, this evidence supports the claim that RAPIBLYK™ offers superior AF prevention and outcome benefits compared to other heart rate control therapies.

In addition, the applicant discussed Perrett et al. (2024), a systematic review and meta-analysis evaluating the efficacy and safety of intravenous (IV) beta blockers in acute AF and AFL, focusing on the role of  $\beta$ -1 receptor selectivity, to support its claim that RAPIBLYK™ offers a new heart rate control option for acute AF patients, including those with CHF and renal impairment. According to the applicant, across 12 randomized controlled trials with 1,152 patients, the study found that: (1) overall, non-selective IV beta blockers were not superior to other pharmacological agents for heart rate control or conversion to sinus rhythm, but (2) outcomes varied significantly depending on the degree of beta-1 selectivity, with RAPIBLYK™ having superior clinical results and the highest beta-1 selectivity. The applicant stated that, in this analysis, a total of 1,152 adult patients were included, with 526 receiving IV beta blockers and 626 receiving comparators such as diltiazem, digoxin, verapamil, flecainide, ibutilide, or placebo. Per the applicant, the patient population had a mean age of 62.4 years, 38 percent were women, and the baseline heart rate averaged 137 bpm. The applicant stated that most patients had AF (78 percent), with 11 percent having AFL. The study's inclusion criteria required adults ( $\geq 18$  years) with AF/AFL needing acute treatment, typically with ventricular rate  $\geq 100$  bpm. According to the applicant, exclusion criteria included obstructive lung disease, recent anti-arrhythmic use, prophylactic therapy, or arrhythmias other than AF/AFL. The applicant stated that the primary endpoints were heart rate reduction and proportion achieving target heart rate, and the secondary endpoints included conversion to sinus rhythm, need for electrical cardioversion, blood pressure changes, AEs (hypotension, bradycardia, leading to drug discontinuation), time to discharge, and mortality. Per the applicant, Perrett et al. (2024) did not

show statistically significant difference between beta blockers and comparators for heart rate reduction (standardized mean difference  $-0.65$  bpm,  $p = 0.19$ ) or achieving the target heart rate (relative risk 0.85,  $p = 0.70$ ). The applicant stated subgroup analysis revealed, however, that (1) conventional selective beta-1 blockers, metoprolol and esmolol, were inferior to diltiazem (relative risk 0.33,  $p < 0.001$ ), and (2) RAPIBLYK™ was superior to digoxin/diltiazem (relative risk 1.98,  $p < 0.001$ ). According to the applicant, safety outcomes indicated no overall difference in hypotension (relative risk 1.85,  $p = 0.11$ ) or bradycardia (relative risk 1.29,  $p = 0.76$ ) compared to controls. The applicant stated that, while non-selective beta blockers were associated with significantly more hypotension ( $p < 0.001$ ) and bradycardia ( $p = 0.003$ ), RAPIBLYK™ did not increase AEs. According to the applicant, this meta-analysis demonstrated that RAPIBLYK™ improved outcomes compared to conventional agents like diltiazem or digoxin (as well as non-selective beta blockers) for acute AF and AFL, achieving superior heart rate control without increasing hypotension or bradycardia. The applicant stated these findings directly support that RAPIBLYK™ offers a valuable new option for patients with AF who also have comorbidities such as CHF or renal impairment, where tolerability and safety are critical.

A few commenters expressed support for new technology add-on payments for RAPIBLYK™ by asserting that there is a population for whom RAPIBLYK™ is a more appropriate treatment option than other beta blockers. Two clinicians stated their belief that improved access to RAPIBLYK™ would benefit critically ill patients who previously had no viable alternatives. The commenters stated that RAPIBLYK™ has been available in Japan and the European Union for years and that its ultra-selective beta-1 blockade provides effective heart rate control with minimal impact on blood pressure, vascular tone, or bronchial tone, enabling safe use in patients with impaired cardiac contractility, renal dysfunction, or advanced heart failure. The commenters also stated that RAPIBLYK™'s rapid onset of action, titratability, and ultra-short half-life and ultra-high selectivity for beta-1 cardio-receptors have been shown to effectively lower heart rate and allows for precise control and efficacy evaluation in the ICU environment, where patients are highly susceptible to adverse drug effects.

A few commenters asserted that RAPIBLYK™ can treat a different patient population compared to other heart rate control drugs, including other beta blockers, as it has demonstrated effective management of tachyarrhythmias, even in patients with impaired cardiac function or at risk of hemodynamic instability or hypotension. The commenters reiterated evidence submitted in the application (Koukoulitsios et al., 2025; Cafaro et al., 2023; Si et al., 2025) and asserted that, based on their clinical experience, there is a clear gap in available and effective heart rate control therapies for these high-risk patient subgroups,<sup>63</sup> including use in critically ill patients, who have shown improved outcomes even compared to other selective beta blockers such as esmolol. The commenters noted that Si et al. (2025) showed that patients in the RAPIBLYK™ group experienced a shorter hospital LOS and a shorter ICU stay, including in the elderly cohort ( $\geq 65$  years old), than patients in the esmolol group. One commenter stated current options often lack the safety and efficacy needed for rapid rate control in unstable patients and asserted that there is a great unmet need for RAPIBLYK™, particularly for his patients with heart failure with reduced ejection fraction and/or shock, where traditional beta blockers pose substantial risks. One commenter stated that current consensus guidelines recommend beta blockers or calcium channel blockers, but these agents are often contraindicated in ICU patients due to risk of hypotension or for patients with impaired cardiac function, while other alternatives, such as amiodarone or digoxin, are limited by toxicities, poor efficacy in high adrenergic states, or unfavorable pharmacokinetics. Another commenter stated that experience with RAPIBLYK™ outside the U.S. has demonstrated the benefits of its use in this patient population, with the European Society of Cardiology (ESC) 2024 Guidelines for the Management of AF stating that RAPIBLYK™ safely controls rapid AF in patients with low ejection fraction with minimal impact on contractility or blood pressure.<sup>64</sup> The

<sup>63</sup> Si X, Yuan H, Shi R, Song W, Guo J, Jiang J, Yang T, Ma X, Wang H, Chen M, Wu J, Guan X, Monnet X. Comparison of the efficacy and safety of Landiolol and Esmolol in critically ill patients: a propensity score-matched study. *Ann Intensive Care*. 2025 Jan 12;15(1):5. <https://doi.org/10.1186/s13613-024-01418-8>.

<sup>64</sup> Van Gelder, IC et al., 2024 ESC Guidelines for the management of atrial fibrillation developed in Collaboration with the European Association for Cardio-Thoracic Surgery (EACTS), *EURO. HEART J*. 00, 1–101. <https://doi.org/10.1093/eurheartj/ehae176>.

commenter cited the RAPIBLYK™ prescribing information, which contains specific dosing instructions for patients with impaired cardiac function, stating that 5 randomized, double-blind, placebo-controlled studies, which included treatment of 317 adults with SVT, showed that within 10 minutes, patients treated with RAPIBLYK™ had a decreased heart rate of 40 to 90 percent compared to 0 to 11 percent for patients treated with placebo.<sup>65</sup> According to the commenter, the availability of RAPIBLYK™ would allow him to stabilize these patients quickly and safely, improving outcomes in the most vulnerable population.

**Response:** We thank the applicant and commenters for their comments. After review of the information provided by the applicant and the public comments received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether RAPIBLYK™ meets the substantial clinical improvement criterion.

While the applicant asserted that RAPIBLYK™ offers a treatment option for patients unresponsive to, or ineligible for, currently available treatments because it offers a new heart rate control option for patients with acute AF and additional co-morbidities, including CHF and renal impairment, we note that we did not receive evidence to identify a patient population that is unresponsive to, or ineligible for, currently available treatments. Although the applicant claimed that the use of non-selective beta blockers and calcium channel blockers for rate control are ineffective or contraindicated in high risk patients, which the applicant defined as those with an ejection fraction (EF) less than 40 percent, we note that beta blockers, including esmolol, a selective beta-1 adrenergic blocker, are not specifically contraindicated for use in patients with an EF less than 40 percent. According to the 2023 Guideline for the Diagnosis and Management of AF<sup>66</sup> provided by

the applicant, patients with an EF less than 40 percent can receive beta blockers, amiodarone, and digoxin for rate control. Additionally, the applicant cited Eslami et al. (2021),<sup>67</sup> a prospective study from 2018 to 2020 consisting of 87 patients with HF or AF with underlying chronic kidney dysfunction which observed that there was a significant relationship between Glomerular Filtration Rate (GFR) and serum digoxin concentration. However, we note that this is not a contraindication to the use of digoxin and that a dose reduction<sup>68</sup> would be recommended.

Regarding the assertion that RAPIBLYK™ significantly improves clinical outcomes relative to services or technologies previously available, we are concerned that we did not receive sufficient evidence to compare RAPIBLYK™ to other available treatments, such as amiodarone. To support its claim that RAPIBLYK™ reduces AF and improves outcomes compared to other heart rate control therapies in patients at high risk for POAF, the applicant provided Koukoulitsios et al. (2025),<sup>69</sup> a prospective, randomized, open-label study consisting of 39 patients in an ICU in General Hospital of Athens from 2018 to 2020 that observed RAPIBLYK™ reduced heart rate (HR) by 40 bpm in comparison to 30 bpm for esmolol at 30 minutes. However, we note that the study did not assess for AF or whether use of RAPIBLYK™ and esmolol reduced AF events. The applicant also cited Cafaro et al. (2023),<sup>70</sup> a systematic review and meta-analysis of nine randomized controlled studies that observed RAPIBLYK™ showed a 12.2

percent incidence in POAF compared to 32.6 percent for the control group. However, while patients treated with RAPIBLYK™ showed a reduction in POAF (56 events in 460 patients) compared to those who received either saline placebo or undefined controls (133 events in 408 patients) ( $p < 0.00001$ ) in the control group, we note that it is difficult to evaluate if RAPIBLYK™ reduces AF and improves outcomes compared to other heart rate control therapies because it is unclear if existing therapies were included as undefined controls.

Similarly, we question whether the provided evidence is sufficient to demonstrate that RAPIBLYK™ leads to improved outcomes, reduced hospital LOS, and reduced ICU LOS in critically ill patients and those with POAF. To support this claim, the applicant submitted one peer-reviewed study (Si et al., 2025),<sup>71</sup> which retrospectively observed RAPIBLYK™ and esmolol's effects in 438 surgical and medical ICU patients (292 receiving esmolol and 146 receiving RAPIBLYK™) with tachycardia, noting that a small subset of patients had AF (9.8 percent). The study observed significantly shorter ICU and hospital LOS in the RAPIBLYK™ group compared to the esmolol group (ICU LOS: 4.9 vs. 6.7 days,  $p = 0.011$ ; hospital LOS: 26.5 vs. 30.0 days,  $p = 0.044$ ). However, we note that the study treated patients with moderate illness severity and used physician preference rather than randomization to determine treatment selection. These design features limit generalizability to critically ill patients and may introduce the potential for selection bias and confounding in the reported outcomes.

After review of the information provided by the applicant and the public comments received in response to the New Technology Town Hall meeting, we are unable to determine that RAPIBLYK™ represents a substantial clinical improvement over existing technologies, and therefore, we are proposing to disapprove FY 2027 new technology add-on payments for RAPIBLYK™.

We are inviting public comments on whether RAPIBLYK™ meets the substantial clinical improvement criterion and our proposal to disapprove new technology add-on payments for RAPIBLYK™ for FY 2027.

<sup>65</sup> AOP Orphan Pharmaceuticals. (2024 November). *RAPIBLYK (landiolol) for injection, for intravenous use: Highlights of Prescribing Information*. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/217202s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217202s000lbl.pdf).

<sup>66</sup> Joglar JA, Chung MK, Armbuster AL, Benjamin EJ, Chyou JY, Cronin EM, Deswal A, Eckhardt L, Goldberger ZD, Gopinathannair R, Gorenek B, Hess PL, Hlatky M, Hogan G, Ibeh C, Indik JH, Kido K, Kusumoto F, Link MS, Linta KT, Marcus GM, McCarthy PM, Patel N, Patton KK, Perez MV, Piccini JP, Russo AM, Sanders P, Streur MM, Thomas KL, Times S, Tisdale JE, Valente AM, Van Wagoner DR. 2023 ACC/AHA/ACCP/HRS guideline for the diagnosis and management of atrial fibrillation: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines.

Circulation. 2024;149:e1–e156. <https://doi.org/10.1161/CIR.0000000000001193>.

<sup>67</sup> Eslami V, Mortezaapour F, Samavat S, Ziaee S, Gheymati A (2021) Evaluating plasma Digoxin concentration after an intravenous loading dose in patients with renal failure. *Arch Clin Nephrol* 7(1): 033–037. <https://dx.doi.org/10.17352/acn>.

<sup>68</sup> Concordia Pharmaceuticals Inc. Prescribing information for Lanoxin (digoxin) injection, for intravenous or intramuscular use; 2025. (Revised 10/2025). Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2025/009330s040lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/009330s040lbl.pdf).

<sup>69</sup> Koukoulitsios G, Tsikritsaki K, Magklaras G, Koutivas AM, Kalogeromitros A, Papaioannou V. Comparison of Landiolol and Esmolol on Haemodynamic Responses During Weaning of Intensive Care Unit Patients with Reduced Ejection Fraction after Vascular Surgery. *Card Fail Rev*. 2025 May 21;11:e13. <https://doi.org/10.15420/cfr.2024.18>.

<sup>70</sup> Cafaro T, Allwood M, McIntyre WF, Park LJ, Daza J, Ofori SN, Ke Wang M, Borges FK, Conen D, Marcucci M, Healey JS, Whitlock RP, Lamy A, Belley-Côté EP, Spence JD, McGillion M, Devereaux PJ. Landiolol for the prevention of postoperative atrial fibrillation after cardiac surgery: a systematic review and meta-analysis. *Can J Anaesth*. 2023 Nov;70(11):1828–1838. <https://doi.org/10.1007/s12630-023-02586-0>.

<sup>71</sup> Si, X., Yuan, H., Shi, R., Song, W., Guo, J., Jiang, J., Yang, T., Ma, X., Wang, H., Chen, M., Wu, J., Guan, X., & Monnet, X. (2025). Comparison of the efficacy and safety of Landiolol and Esmolol in critically ill patients: a propensity score-matched study. *Annals of intensive care*, 15 (1), 5. <https://doi.org/10.1186/s13613-024-01418-8>.

f. WASKYRA™ (etuvetidigene autotemcel)

Fondazione Telethon submitted an FY 2027 application for new technology add-on payments for WASKYRA™. According to the applicant, WASKYRA™ is a one-time, cell-based autologous gene therapy indicated for the treatment of pediatric patients 6 months and older and adults with Wiskott-Aldrich Syndrome (WAS) who have a mutation in the *WAS* gene for

whom hematopoietic stem cell transplantation (HCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available. Per the applicant, following reduced-intensity conditioning, WASKYRA™ is administered intravenously as a single autologous infusion of gene-corrected cluster of differentiation (CD)34+ hematopoietic stem and progenitor cells (HSPCs), with a minimum recommended dose of  $7.0 \times 10^6$  CD34+

cells/kg, individualized by patient weight and leukapheresis yield.

The following table provides an overview of the new technology add-on payment application for WASKYRA™ and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP2510033XJPK>.

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|                                            |                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                      | Preliminary CMS Assessment |
|--------------------------------------------|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Unique ICD-10-PCS code(s)                  |                        | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                        | N/A.                       |
| Newness Criterion                          | Newness Period         | BLA approved on December 9, 2025, for the treatment of pediatric patients aged 6 months and older and adults with WAS who have a mutation in the <i>WAS</i> gene for whom HCT is appropriate and no suitable HLA-matched related stem cell donor is available.<br><br>Commercial delay expected until March 31, 2026.                                                                                                                     | See following discussion.  |
|                                            | Substantial Similarity | Treats a new disease and/or a new patient population.                                                                                                                                                                                                                                                                                                                                                                                     | See following discussion.  |
| Cost Criterion                             |                        | Scenario 1: 110 claims mapping to 10 MS-DRGs, with none exceeding 10.0% of the total identified cases.<br><br>Scenario 2: 99 claims mapping to 9 MS-DRGs, with none exceeding 11.1% of the total identified cases.<br><br>Final inflated average case-weighted standardized charge per case (Scenario 1 – \$16,446,982; Scenario 2 – \$16,469,706) exceeded the average case-weighted threshold amount (Scenarios 1 and 2 – \$1,885,660). | Meets cost criterion.      |
| Substantial Clinical Improvement Criterion |                        | Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments.<br><br>Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.<br><br>Provided no published or unpublished studies assessing the technology, practice guidelines, or other information.                                    | See following discussion.  |

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#### Newness Criterion

The applicant stated that the technology would not be commercially available until March 31, 2026, due to the applicant's need to establish commercial infrastructure, finalize import logistics, and plan for U.S. market compliance. We are interested in additional information regarding when the technology first became available for sale and the cause of any delay in the technology's commercial availability, such as additional details regarding the establishment of commercial infrastructure.

Regarding substantial similarity, the applicant asserted that WASKYRA™

treats a new disease and/or a new patient population because it is a curative treatment designed for patients lacking a suitable HCT donor and noted that HCT is limited by donor availability, age, and risk of graft failure or graft-versus-host disease. However, based on information available at the time of this proposed rule, we disagree with the applicant that WASKYRA™ treats a new disease or new patient population because there are several other therapies FDA-approved for WAS in patients that cannot receive a HCT, such as ALYGLO™ and ASCENIV™ which are indicated for treatment of primary humoral immunodeficiency in patients with WAS and corticosteroids indicated for eczema. We note that the

applicant did not assert that WASKYRA™ has a new mechanism of action compared to existing treatments for WAS or that it changes the MS-DRG assignment. Therefore, based on information available at the time of this proposed rule, it is unclear whether WASKYRA™ is substantially similar to existing treatments.

We are inviting public comments on whether WASKYRA™ is substantially similar to existing technologies and whether WASKYRA™ meets the newness criterion.

#### Cost Criterion

Regarding the cost criterion, we agree with the applicant that the technology meets the cost criterion. We are inviting

public comments on whether WASKYRA™ meets the cost criterion. Substantial Clinical Improvement Criterion

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for WASKYRA™.

After review of the information provided by the applicant, we have the following concerns regarding whether WASKYRA™ meets the substantial clinical improvement criterion. We note that the applicant did not provide any evidence to support its claims, as further discussed in this section, as to why the technology represents a substantial clinical improvement over existing technologies. We are unable to evaluate substantial clinical improvement in the absence of supporting evidence.

Furthermore, with respect to the applicant's claims, we note that the applicant asserted that WASKYRA™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments because it provides a treatment option for WAS patients without HLA-identical related donors. However, we note that this claim does not explain why these patients would be ineligible for HCT with an HLA-matched unrelated donor. In addition, while the applicant claimed that WASKYRA™ reduces WAS disease burden, offers a safer disease-modifying

option for patients eligible for HCT, demonstrates sustained engraftment of gene-corrected cells and long-term clinical benefit, and directly addresses the genetic defect underlying WAS through lentiviral gene transfer, we note that these claims do not identify a patient population that is unresponsive to, or ineligible for, currently available supportive care treatments and HCT. We further note that the applicant asserted that WASKYRA™ significantly improves clinical outcomes relative to services or technologies previously available, but did not identify specific outcomes. For example, the applicant claimed that WASKYRA™ offers a safer option for WAS patients compared to HCT, but did not describe a clinical outcome, such as a reduction in at least one clinically significant adverse event as provided by § 412.87(b)(1)(ii)(C)(1). Also, as previously noted, the applicant did not provide evidence to support any of its claims and therefore we are unable to evaluate whether WASKYRA™ represents a substantial clinical improvement over existing technologies.

After review of the information provided by the applicant, we are unable to determine that WASKYRA™ represents a substantial clinical improvement over existing technologies, and therefore, we are proposing to disapprove new technology add-on payments for WASKYRA™ for FY 2027.

We are inviting public comments on whether WASKYRA™ meets the substantial clinical improvement criterion and our proposal to disapprove new technology add-on payments for WASKYRA™ for FY 2027.

g. YARTEMLEA® (narsoplimab-wuug)

Omeros Corporation submitted an FY 2027 application for new technology add-on payments for YARTEMLEA® (narsoplimab-wuug). According to the applicant, YARTEMLEA® is a fully human monoclonal antibody designed to treat and alleviate the detrimental consequences of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA) by targeting and inhibiting mannan-binding lectin-associated serine protease 2 (MASP-2), an effector enzyme that activates the lectin pathway of the complement system. YARTEMLEA® is administered as a 30-minute intravenous infusion once weekly, and the recommended dose is 370 mg for patients greater than or equal to 50 kg and is 4 mg/kg for patients weighing less than 50 kg. The applicant estimated that patients receive an average total dosage of 4,218 mg per inpatient stay. We note that the applicant submitted an application for new technology add-on payments for this technology for FY 2022 (86 FR 25282 through 25286; 86 FR 44979) and FY 2023 (87 FR 28274 through 28279; 87 FR 48920).

The following table provides an overview of the new technology add-on payment application for YARTEMLEA® and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251006R7LMC>.

|                                                   |                               | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                              | Preliminary CMS Assessment                        |
|---------------------------------------------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Unique ICD-10-PCS code(s)</b>                  |                               | XW03357 and 7XW04357                                                                                                                                                                                                                                                                                                                                                                                                              | No concerns.                                      |
| <b>Newness</b>                                    | <b>Newness Period</b>         | BLA approved on December 23, 2025, for the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell TA-TMA.                                                                                                                                                                                                                                                                                | Newness date: December 23, 2025                   |
|                                                   | <b>Substantial Similarity</b> | Uses a new mechanism of action.<br><br>Maps to a new MS-DRG.<br><br>Treats a new disease and/or a new patient population.                                                                                                                                                                                                                                                                                                         | Not substantially similar to existing treatments. |
| <b>Cost Criterion</b>                             |                               | 176 claims mapping to 16 MS-DRGs, with none exceeding more than 6.25% of the total identified cases.<br><br>Final inflated average case-weighted standardized charge per case (\$178,290) exceeded the average case-weighted threshold amount (\$117,676).                                                                                                                                                                        | Meets cost criterion.                             |
| <b>Substantial Clinical Improvement Criterion</b> |                               | Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments.<br><br>Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.<br><br>Provided 4 published and 1 unpublished studies assessing the technology, 9 studies assessing comparator technologies, and other information. | See following discussion.                         |

#### Newness Criterion

Regarding substantial similarity, based on the information available at the time of this proposed rule, we agree with the applicant that YARTEMLEA® has a new mechanism of action and treats a new type of disease or patient population compared to existing technology, because YARTEMLEA® is the only FDA-approved therapy indicated for the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell TA-TMA. We note that we disagree with the applicant that YARTEMLEA® is assigned to a different MS-DRG compared to existing technology because patients diagnosed with TA-TMA, including those treated with YARTEMLEA®, map to MS-DRGs 545–547. Therefore, based on information available at the time of this proposed rule, we believe that YARTEMLEA® is not substantially similar to existing technology and meets the newness criterion. We consider the beginning of the newness period to commence on December 23, 2025, the date on which YARTEMLEA® received FDA market authorization for this indication.

We are inviting public comments on whether YARTEMLEA® is substantially similar to existing technologies and whether YARTEMLEA® meets the newness criterion.

#### Cost Criterion

Regarding the cost criterion, we agree with the applicant that the technology meets the cost criterion. We are inviting

public comments on whether YARTEMLEA® meets the cost criterion.

#### Substantial Clinical Improvement Criterion

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for YARTEMLEA®.

After review of the information provided by the applicant, we agree with the applicant that YARTEMLEA® is the first and only FDA-approved treatment option for patients who develop TA-TMA and offers a treatment option for patients who have failed prior treatment with other available therapies including C5 inhibitors and other TA-TMA directed therapies with a one-year overall survival (OS) of 42.7 percent (95% CI: 19.7, 65.8) in adult patients.<sup>72</sup> Therefore, we agree that YARTEMLEA® would offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. Based on the information available at the time of this proposed rule, because YARTEMLEA® appears to meet the criteria for approval for new technology add-on payments, we are proposing to approve YARTEMLEA® for

<sup>72</sup> Schoettler ML, Pusarla SK, Nangia N, et al. Narsoplimab Results in Excellent Survival in Adults and Children With Hematopoietic Cell Transplant Associated Thrombotic Microangiopathy (TA-TMA). *Am J Hematol*. 2025d Aug 29. <https://doi.org/10.1002/ajh.70044>. Epub ahead of print.

new technology add-on payments for FY 2027.

We are inviting public comments on whether YARTEMLEA® meets the substantial clinical improvement criterion and on our proposal to approve YARTEMLEA® for new technology add-on payments.

#### h. ZEVASKYN™ (prademagene zamikeracel)

Abeona Therapeutics®, Inc. submitted an FY 2027 application for new technology add-on payments for ZEVASKYN™. According to the applicant, ZEVASKYN™ is an autologous cell sheet-based gene therapy which contains functional copies of the *collagen type VII alpha 1 chain (COL7A1)* transgene for the treatment of adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). The applicant stated that autologous patient material procured by two 8mm punch biopsies will produce up to twelve 5.5 cm x 7.5 cm gene-corrected cellular sheets available for application in a single surgical session. The number of gene-corrected cellular sheets produced and available for application is not dependent on body size or age. The recommended dose of ZEVASKYN is based on the surface area of the wound(s).

The following table provides an overview of the new technology add-on payment application for ZEVASKYN™ and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online

application posting at <https://>

[mearis.cms.gov/public/publications/  
ntap/NTP251003GPVPQ](https://www.fda.gov/oc/medwatch/publications/ntap/NTP251003GPVPQ).  
BILLING CODE 4120-01-P

|                                                   |                               | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                              | Preliminary CMS Assessment |
|---------------------------------------------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| <b>Unique ICD-10-PCS code(s)</b>                  |                               | XHR0XGA, XHR1XGA, XHR2XGA, XHR3XGA, XHR4XGA, XHR5XGA, XHR6XGA, and XHR7XGA                                                                                                                                                                                                                                                                                                                                                        | No concerns.               |
| <b>Newness Criterion</b>                          | <b>Newness Period</b>         | BLA approval on April 28, 2025, for the treatment of wounds in adult and pediatric patients with RDEB.<br><br>Commercial delay to June 15, 2025.                                                                                                                                                                                                                                                                                  | See following discussion.  |
|                                                   | <b>Substantial Similarity</b> | Uses a new mechanism of action.<br><br>Maps to a new MS-DRG.<br><br>Treats a new disease and/or a new patient population.                                                                                                                                                                                                                                                                                                         | See following discussion.  |
|                                                   | <b>Cost Criterion</b>         | 33 claims mapping to 3 MS-DRGs, with 33.33% of claims mapping to each MS-DRG 576 (Skin Graft Except for Skin Ulcer or Cellulitis with MCC), 577 (Skin Graft Except for Skin Ulcer or Cellulitis with CC), and 595 (Major Skin Disorders with MCC).<br><br>Final inflated average case-weighted standardized charge per case (\$3,653,712) exceeded the average case-weighted threshold amount (\$115,388).                        | Meets cost criterion.      |
| <b>Substantial Clinical Improvement Criterion</b> |                               | Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments.<br><br>Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.<br><br>Provided 2 published and 2 unpublished studies assessing the technology, 4 studies assessing comparator technologies, and other information. | See following discussion.  |

#### BILLING CODE 4120-01-C

##### Newness Criterion

Regarding commercial availability, the applicant stated that ZEVASKYN™ became available for sale on June 15, 2025, 2 months after it received BLA approval on April 28, 2025, because the applicant needed to onboard and train hospitals on the proper procedures for collecting specimens and applying the technology. We are interested in additional information regarding the cause of any delay in the technology's commercial availability, including whether ZEVASKYN™ was available for purchase before June 15, 2025, during the period the applicant trained hospitals.

Regarding substantial similarity, based on the information available at the time of this proposed rule, we agree with the applicant that ZEVASKYN™ uses a new mechanism of action of transducing the full-length *COL7A1* gene into a patient's own keratinocytes to create up to 12 gene-corrected cellular sheets for the treatment of RDEB wounds, as compared to VYJUVEK®, a topical gene therapy that delivers a functional copy of the *COL7A1* gene to affected skin cells using a non-

replicating HSV-1 vector and FILSUVEZ®, a botanical gel with an unknown mechanism of action. We also agree that ZEVASKYN™ maps to a new MS-DRG as compared to VYJUVEK® and FILSUVEZ®. We note that we disagree that ZEVASKYN™ does not treat the same or similar type of disease or the same or similar patient population when compared to existing technology because other therapies, such as VYJUVEK® and FILSUVEZ®, are available to treat wounds in adult and pediatric patients with dystrophic epidermolysis bullosa (DEB), of which RDEB is a subtype. Therefore, based on information available at the time of this proposed rule, we believe that ZEVASKYN™ is not substantially similar to existing technology and meets the newness criterion.

We are inviting public comments on whether ZEVASKYN™ is substantially similar to existing technologies and whether ZEVASKYN™ meets the newness criterion.

##### Cost Criterion

Regarding the cost criterion, we agree with the applicant that the technology meets the cost criterion. We are inviting

public comments on whether ZEVASKYN™ meets the cost criterion.

##### Substantial Clinical Improvement Criterion

Regarding substantial clinical improvement, we also received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ZEVASKYN™, which we are summarizing in this section.

*Comment:* The applicant submitted a public comment in response to questions posed at the Town Hall meeting. With regard to a question as to how wound healing was defined in the phase III VIITAL clinical trial,<sup>73</sup> the applicant stated that wound healing was a co-primary end point and was

<sup>73</sup> Tang JY, Marinkovich MP, Wiss K, McCarthy D, Truesdale A, Chiou AS, Eid E, McIntyre JK, Bailey I, Furukawa LK, Gorell ES, Harris N, Khosla RK, Peter Lorenz H, Lu Y, Nazaroff J, Grachev ID, Moore AJ. Prademagene zamikeracel for recessive dystrophic epidermolysis bullosa wounds (VIITAL): a two-centre, randomised, open-label, intrapatient-controlled phase 3 trial. *Lancet*. 2025 Jul 12;406(10499):163–173. [https://doi.org/10.1016/S0140-6736\(25\)00778-0](https://doi.org/10.1016/S0140-6736(25)00778-0).

measured by visual skin examination by the study investigator, a dermatologist with significant epidermolysis bullosa expertise. Per the applicant, the VIITAL study categorized wound healing into the following brackets: (1) healing at less than 50 percent of baseline, (2) greater than or equal to 50 percent to less than 75 percent of baseline, and (3) greater than or equal to 75 percent of baseline; healing greater than or equal to 75 percent of baseline was assessed as complete wound closure with complete wound healing defined as re-epithelialization with no drainage or erosion and only minor crusting. The applicant stated that the co-primary endpoint evaluated greater than or equal to 50 percent healing from baseline at week 24, and exploratory endpoints further assessed greater than or equal to 75 percent healing. According to the applicant, these definitions ensured consistent, prespecified evaluation across all treated wounds.

With regard to a question inquiring whether the study (Tang et al., 2025) biopsied skin as part of the co-primary endpoint, the applicant stated that the investigators did not use biopsies to evaluate the greater than or equal to 50 percent wound healing co-primary endpoint. Per the applicant, consistent with standard dermatologic practice where wound healing is assessed through clinical and visual examination rather than routine biopsies, the study used photographic and investigator assessments to evaluate the endpoint. According to the applicant, the study's investigators only performed biopsies in the early phase of the long-term follow-up study to confirm anchoring fibrils and C7 production up to 2 years after treatment with ZEVASKYN™.<sup>74</sup> Beyond 2 years, the applicant stated that the study discontinued biopsies due to ethical considerations and because patients refused repeated biopsies of healed skin. The applicant noted that efficacy data extends out to 8 years, with continued planned follow-up of these study subjects extending to up to 15 years.

With regard to a question about the comparison of ZEVASKYN™ to other therapies and the size of treated wound areas, the applicant stated that the 200 cm<sup>2</sup> reference reflects the maximum weekly treatable area for VYJUVEK®, not ZEVASKYN™, which is supplied as up to 12 credit-card sized cellular sheets per treatment cycle (Tang et al., 2023).

Per the applicant, these sheets may be sutured onto separate discrete wounds or joined together on larger wound areas, covering up to 495 cm<sup>2</sup> of wound surface area in a single session. The applicant stated that some patients in ZEVASKYN™ clinical trials had single large wounds while others had multiple separate chronic wounds each greater than or equal to 20 cm<sup>2</sup>. According to the applicant, the study did not permit patients to receive other RDEB therapies while participating in the study, and there are no head-to-head studies of ZEVASKYN™ with VYJUVEK® or FILSUVEZ®. The applicant asserted that head-to-head studies are not required for purposes of determining substantial clinical improvement under the new technology add-on payment criteria. According to the applicant, ZEVASKYN™'s ability to cover up to 495 cm<sup>2</sup> of wound surface area in a single, one-time treatment is a key reason that it is a substantial clinical improvement that addresses an ongoing unmet need for RDEB patients notwithstanding the availability of VYJUVEK® and FILSUVEZ®.

With regard to a question about the definition of a large, chronic wound, the applicant stated that large, chronic wounds for RDEB generally means a wound that is greater than 20 cm<sup>2</sup> and open for more than 6 months.

The applicant also reiterated information from its application regarding the current RDEB treatment landscape, ZEVASKYN™'s clinical profile and durability, and the key features that distinguish ZEVASKYN™ from other available RDEB therapies.

*Response:* We thank the applicant for its comments. After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether ZEVASKYN™ meets the substantial clinical improvement criterion.

Regarding the assertion that ZEVASKYN™ offers a treatment option for a patient population unresponsive to, or ineligible for, current available treatments, we note that the claims and supporting evidence do not identify a patient population treated with ZEVASKYN™ who cannot otherwise receive existing treatments, such as VYJUVEK® or FILSUVEZ®. The applicant claimed that RDEB patients suffer from severe large wounds that are highly debilitating and there currently are no treatments available to address large chronic RDEB wounds. However, we note that both VYJUVEK® and FILSUVEZ® do not have a maximum

dose in their prescribing label<sup>75 76</sup> that would preclude the use of either treatment in difficult-to-treat large and chronic RDEB wounds. Similarly, the applicant claimed that no currently available treatment options effectively target chronic pain and itching experienced by RDEB patients and that chronic RDEB wounds pose a high risk of developing squamous cell carcinoma (SCC) and multiple systemic infections, stating that ZEVASKYN™ is the only approved therapy that provides durable healing for these wounds. However, neither the presence of chronic pain and itching nor a high risk of developing SCC and multiple systemic infections preclude these patients from receiving treatment with VYJUVEK® or FILSUVEZ®. Accordingly, we question whether these claims describe improvements in clinical outcomes over existing therapies rather than identifying a distinct patient population unresponsive to, or ineligible for, current available treatments that ZEVASKYN™ can treat.

In addition, while the applicant asserted that ZEVASKYN™ significantly improves clinical outcomes for patients with RDEB, we note that we did not receive sufficient evidence comparing ZEVASKYN™ to currently available treatments. The applicant stated that ZEVASKYN™ is the only autologous, cell-based gene therapy to demonstrate significantly improved wound healing even in the most difficult-to-treat large and chronic RDEB wounds; however, we note that both VYJUVEK® and FILSUVEZ® demonstrated statistically significant wound healing in their respective clinical trials. Therefore, we question whether ZEVASKYN™ significantly improves wound healing compared to these treatments. The applicant had cited Tang et al. (2025),<sup>77</sup> a randomized, open-label, intra-patient-controlled phase 3 trial that included 11 RDEB patients who had 86 matched and

<sup>75</sup> Krystal Biotech, Inc. (2025, Sept.) VYJUVEK® (beremagene geperpavec-svdt) biological suspension mixed with excipient gel for topical application: highlights of prescribing information. <https://www.krystallabel.com/pdf/vyjuvek-us-pi.pdf>.

<sup>76</sup> Chiesi USA, Inc. (2024, May.) FILSUVEZ® (birch triterpenes) topical gel: highlights of prescribing information. [https://resources.chiesiusa.com/Filsuvez/FILSUVEZ\\_PI.pdf](https://resources.chiesiusa.com/Filsuvez/FILSUVEZ_PI.pdf).

<sup>77</sup> Tang JY, Marinkovich MP, Wiss K, McCarthy D, Truesdale A, Chiou AS, Eid E, McIntyre JK, Bailey I, Furukawa LK, Gorell ES, Harris N, Khosla RK, Peter Lorenz H, Lu Y, Nazaroj J, Grachev ID, Moore AJ. Prademagene zamikeracel for recessive dystrophic epidermolysis bullosa wounds (VIITAL): a two-centre, randomised, open-label, intrapatient-controlled phase 3 trial. *Lancet*. 2025 Jul 12;406(10499):163–173. [https://doi.org/10.1016/S0140-6736\(25\)00778-0](https://doi.org/10.1016/S0140-6736(25)00778-0).

<sup>74</sup> Abeona Therapeutics, Inc. (2024, June 27). A Long-Term Extension Study for Participants Previously Treated With EB-101 for the Treatment of RDEB (Study No. NCT05708677). [ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT05708677](https://clinicaltrials.gov/study/NCT05708677).

randomized wound pairs treated with either ZEVASKYN™ or control such as daily bandaging and other palliative measures. This study observed that 81 percent of ZEVASKYN™-treated wounds were at least 50 percent healed from baseline compared with 16 percent of control wounds (mean difference: 67 percent; 95 percent CI: 50–89,  $p = <0.0001$ ) and that complete wound healing from baseline was observed in 16 percent of ZEVASKYN™-treated wounds compared to 0 percent of control wounds (mean difference 13 percent; 95 percent CI 2–26,  $p = 0.016$ ). However, we note that in Guide et al. (2022),<sup>78</sup> a double-blind intra-patient randomized, placebo-controlled phase 3 trial consisting of 31 patients (30 with RDEB) who received either VYJUVEK® or placebo weekly for 26 weeks, 65 percent of patients achieved complete wound closure with VYJUVEK® compared to 26 percent with placebo. Similarly, in Kern et al. (2023),<sup>79</sup> a randomized, double-blind, placebo-controlled phase 3 trial consisting of 223 patients (175 with RDEB) who received either FILSUEVZ® or placebo, 44 percent of RDEB patients treated with FILSUEVZ® achieved first complete closure of the target wound within 45 days compared to 26.2 percent of the patients who received placebo.

The applicant also asserted that ZEVASKYN™ is the only treatment for RDEB that has demonstrated significant reductions in both pain and itch and that ZEVASKYN™ results in durable wound healing. However, we note that the comparator data we received did not specifically measure pain and itch, and follow-up time for wound healing was limited to 6 months for VYJUVEK® and 90 days for FILSUEVZ®, which limits meaningful comparisons to ZEVASKYN™. Additionally, although the applicant asserted that ZEVASKYN™ provides durable wound healing following a single treatment application, we are concerned that wounds that have not achieved complete closure may require additional treatment, which raises questions regarding the durability of the treatment

and whether this can be considered a one-time treatment as asserted by the applicant. According to So et al. (2022),<sup>80</sup> a single-center, non-randomized, open-label phase I/IIa trial that included seven patients who received ZEVASKYN™ on 38 chronic wounds while following patients for a mean of 5.9 years (range: 4–8 years), 70 percent of ZEVASKYN™-treated sites had greater than or equal to 50 percent wound healing and 63 percent had greater than or equal to 75 percent wound healing at 5 years. We note that given that a subset of treated wounds achieved complete closure and a substantial proportion demonstrated only partial healing, we are uncertain that a single application of ZEVASKYN™ is sufficient and durable for all patients.

Furthermore, we note that although the applicant asserted that ZEVASKYN™ has a favorable safety profile with no serious treatment-emergent adverse events (TEAEs) related to the study treatment and no reports of SCC in ZEVASKYN-treated wounds, the applicant did not compare this with TEAEs and rates of SCC seen with available treatments such as VYJUVEK® and FILSUEVZ®. Therefore, we cannot determine an improvement in safety for ZEVASKYN™ over existing technologies.

After review of the information provided by the applicant and the public comments received in response to the New Technology Town Hall meeting, we are unable to determine that ZEVASKYN™ represents a substantial clinical improvement over existing technologies, and therefore, we are proposing to disapprove new technology add-on payments for ZEVASKYN™ for FY 2027.

We are inviting public comments on whether ZEVASKYN™ meets the substantial clinical improvement criterion and our proposal to disapprove new technology add-on payments for ZEVASKYN™ for FY 2027.

#### 6. Proposed FY 2027 Applications for New Technology Add-On Payments (Alternative Pathways)

As discussed previously, beginning with applications for FY 2021, a medical device designated under FDA's Breakthrough Devices Program that has received marketing authorization as a Breakthrough Device, for the indication covered by the Breakthrough Device designation, may qualify for the new

technology add-on payment under an alternative pathway. Additionally, beginning with FY 2021, a medical product that is designated by FDA as a Qualified Infectious Disease Product (QIDP) and has received marketing authorization for the indication covered by the QIDP designation, and, beginning with FY 2022, a medical product that is a new medical product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway, may also qualify for the new technology add-on payment under an alternative pathway. Under an alternative pathway, a technology will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still be within the 2-to-3-year newness period to be considered "new," and must also still meet the cost criterion. We refer readers to section II.H.8. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58715 through 58733) for further discussion of the alternative new technology add-on payment pathways for these technologies. As previously noted, in section II.E.7. of this proposed rule, we are proposing to repeal the alternative pathway for new technology add-on payment beginning with applications received for new technology add-on payments for FY 2028 and require all applicants for new technology add-on payments to demonstrate that they meet all eligibility requirements to receive add-on payments. (We refer readers to section II.E.7. of this proposed rule for a complete discussion regarding this proposal.)

As discussed previously, as finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990) and subsequently updated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36662 through 36664), we publicly post online applications for new technology add-on payment beginning with FY 2024 applications. As noted in those final rules, we are continuing to provide discussion of the concerns or issues we identified with respect to applications submitted under the alternative pathway, but we are providing more succinct information as part of the summaries in the proposed and final

<sup>78</sup> Guide, S. V., Gonzalez, M. E., Bağcı, I. S., Agostini, B., Chen, H., Feeney, G., Steimer, M., Kapadia, B., Sridhar, K., Quesada Sanchez, L., Gonzalez, F., Van Ligten, M., Parry, T. J., Chitra, S., Kammerman, L. A., Krishnan, S., & Marinkovich, M. P. (2022). Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa. *New England Journal of Medicine*, 387(24), 2211–2219. <https://doi.org/10.1056/NEJMoa2206663>.

<sup>79</sup> Kern, J. S., Sprecher E., Fernandez M. F., et al. Efficacy and safety of Oleogel-S10 (birch triterpenes) for epidermolysis bullosa: results from the phase III randomized double-blind phase of the EASE study. *British Journal of Dermatology*, 188(1), 12–21, <https://doi.org/10.1093/bjd/ljac001>.

<sup>80</sup> So JY. et al. Long-term safety and efficacy of gene-corrected autologous keratinocyte grafts for recessive dystrophic epidermolysis bullosa. *Orphanet Journal of Rare Diseases*. 2022(17):377. <https://doi.org/10.1186/s13023-022-02546-9>.



rules regarding the applicant's assertions as to how the medical service or technology meets the applicable new technology add-on payment criteria. We refer readers to <https://mearis.cms.gov/public/publications/ntap> for the publicly posted FY 2027 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted), including tables listing the ICD-10-CM codes, ICD-10-PCS codes, and/or MS-DRGs related to the analyses of the cost criterion for certain technologies for the FY 2027 new technology add-on payment applications.

In addition, for certain FY 2027 new technology add-on payment applications, we are making available separate tables listing the ICD-10-PCS codes or ICD-10-CM codes that would be used to identify the Breakthrough Device-designated indication, or would be appropriate to exclude for cases related to a different technology, for purposes of the new technology add-on payment, if approved, in Table 10 associated with this proposed rule, available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps>. To access Table 10, click on the link titled "FY 2027 IPPS Proposed Rule Home Page" or "Acute Inpatient—Files for Download" on the left side of the screen, at the CMS website. Please see section VI of the Addendum for additional information regarding tables associated with this proposed rule.

We received 32 applications for new technology add-on payments for FY 2027 under the new technology add-on payment alternative pathway. As previously discussed, beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant

has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 and FY 2025 IPPS/LTCH PPS final rules (88 FR 58948 through 58958; 89 FR 69242 through 69245). Of the 32 applications received under the alternative pathway, 7 applications were not eligible for consideration for new technology add-on payment because they did not meet these requirements; and 3 applicants withdrew their applications prior to the issuance of this proposed rule. For the remaining 22 applications, all of the technologies received a Breakthrough Device designation from FDA.

In accordance with the regulations under § 412.87(f)(2), applicants for new technology add-on payments for FY 2027 for Breakthrough Devices must have FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Under § 412.87(f)(3), applicants for new technology add-on payments for FY 2027 for QIDPs and technologies approved under the LPAD pathway must have FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. The policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742) provides for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) at § 412.87(d) that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments. We refer the reader to the FY 2021 IPPS/LTCH final rule for a complete discussion of this policy (85 FR 58737 through 58742).

As we did in the FY 2026 IPPS/LTCH PPS proposed rule, for applications under the alternative new technology add-on payment pathway, in this proposed rule we are making a proposal to approve or disapprove each of these 22 applications for FY 2027 new technology add-on payments. Therefore, in this section of the preamble of this proposed rule, we provide an overview table of the new technology add-on

payment application and CMS's preliminary assessment for each alternative pathway application, and propose whether or not each technology would be eligible for the new technology add-on payment for FY 2027.

We note that we received multiple applications for subscription-based technologies for FY 2027. As stated in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58630) and in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69207), we understand that there are unique circumstances with respect to determining a cost per case for a technology that utilizes a subscription for its cost and we will continue to consider the issues relating to calculation of the cost per unit of technologies sold on a subscription basis as we gain more experience in this area. We continue to welcome comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for add-on payment.

#### a. Alternative Pathway for Breakthrough Devices

##### 1. Bayesian Health Sepsis Flagging Device

Bayesian Health, Inc. submitted a FY2027 application for new technology add-on payments for the Bayesian Health Sepsis Flagging Device. According to the applicant, the Bayesian Health Sepsis Flagging Device is artificial intelligence and machine learning-based Software as a Medical Device (SaMD) intended for use in conjunction with clinical assessments and other laboratory findings to aid the early detection and/or risk prediction of sepsis within the next 4 days.

The following table provides an overview of the new technology add-on payment application for the Bayesian Health Sepsis Flagging Device and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/publications/ntap/NTP25100520EEP>.

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|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Preliminary CMS Assessment                     |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | N/A                                            |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> Targeted Real-time Early Warning System (TREWS) is artificial intelligence and machine learning-based software as a medical device intended for use in conjunction with clinical assessments and other laboratory findings to aid the early detection and/or risk prediction of sepsis within the next 4 days. TREWS uses a machine learning algorithm to analyze patient data from the Electronic Healthcare Record (EHR), which includes a combination of the following variables: patient information, comorbidities, the chief complaint documented at presentation to the emergency department, laboratory measurements and vital signs, and procedures, medications, and consult orders. TREWS outputs a semi-quantitative flag (“high risk for sepsis” and “risk for sepsis”) that is displayed within the EHR. TREWS is to be used in combination with other clinical and laboratory data by healthcare providers when providing patient care. TREWS is indicated for use in adult patients in the emergency, observation, general ward, and intensive care units. TREWS is intended to be used upon ED presentation or hospital admission throughout the duration of the patient’s stay. TREWS is a prescription-use only device.</p> <p>Per the applicant, the Targeted Real-time Early Warning System (TREWS) device named in the Breakthrough Device designation letter is the same device as the Bayesian Health Sepsis Flagging Device.</p> <p><b>FDA Indication:</b> Pending.</p> | Pending FDA marketing authorization.           |
| <b>Newness Period</b>                  | Applicant anticipates FDA decision by May 1, 2026, consistent with its Breakthrough Device designation. No commercial availability delay expected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Pending FDA marketing authorization.           |
| <b>Cost Criterion</b>                  | <p>Scenarios 1 and 2: 3,498,833 claims mapping to 739 MS-DRGs, with 14.67 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV &gt;96 Hours with MCC).</p> <p>Final inflated average case-weighted standardized charge per case (Scenario 1 – \$83,896; Scenario 2 – \$81,748) exceeded the average case-weighted threshold amount (Scenarios 1 and 2 – \$73,678).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Meets cost criterion.                          |
| <b>Technology Cost</b>                 | The cost of the Bayesian Health Sepsis Flagging Device is a subscription that is tiered based on the bed size of the hospitals in the seven health systems currently using the technology, and the average cost per patient per health system will vary based on the number of hospital stays where the technology is used. An average cost to the hospital per patient of \$95.14 was estimated, based on total costs for inpatient use of the technology divided by total inpatient stays across the seven health systems. The overall cost per case was then calculated as the sum of costs-per-case across the seven health systems, divided by the number of health systems.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Maximum new technology add-on payment: \$61.84 |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the Bayesian Health Sepsis Flagging Device meets the cost criterion and are therefore proposing to approve the Bayesian Health Sepsis Flagging Device for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of the Bayesian Health Sepsis Flagging

Device would be \$61.84 for FY 2027 (that is, 65 percent of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the Bayesian Health Sepsis Flagging Device meets the cost criterion and our proposal to approve new technology add-on payments for the Bayesian Health Sepsis Flagging Device for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

#### 2. BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT Body

Aidoc Medical Ltd., Inc. submitted a FY2027 application for new technology add-on payments for BriefCase-Triage: CARE Multi-Triage CT Body (BriefCase-Triage). According to the applicant, BriefCase-Triage is a radiological triage device used for the analysis of contrast and non-contrast CT images that flags and communicates suspected positive findings for a wide range of clinically actionable, time-sensitive conditions in the abdominopelvic region.

The following table provides an overview of the new technology add-on payment application for BriefCase-Triage and CMS’s preliminary assessment. For additional details

provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251004A9NVV>.

|                                 | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Preliminary CMS Assessment                                                     |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Unique ICD-10-PCS Code(s)?      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | N/A                                                                            |
| Breakthrough Device Requirement | <p><b>Breakthrough Device Designation Indication:</b> BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT Body is a radiological computer aided triage and notification software for use in the analysis of contrast and non-contrast CT images of the chest, abdomen, and/or pelvis, in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive findings, per study, of: diverticulitis; abdominal-pelvic abscess; appendicitis; intestinal ischemia and/or pneumatosis; obstructive renal stone; small bowel obstruction; large bowel obstruction; spleen injury; liver injury; kidney injury; and pelvic fracture.</p> <p><b>FDA Indication:</b> BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT Body is a radiological computer aided triage and notification software indicated for use in the analysis of contrast and non-contrast CT images of the chest, abdomen, and/or pelvis, in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive findings, per study, of: 1. Diverticulitis; 2. Abdominal-pelvic abscess; 3. Appendicitis; 4. Intestinal ischemia and/or pneumatosis; 5. Obstructive renal stone; 6. Small bowel obstruction; 7. Large bowel obstruction; 8. Spleen injury; 9. Liver injury; 10. Kidney injury; 11. Pelvic fracture.</p> <p>The device flags cases with at least one suspected finding to assist with triage/prioritization of medical images. The device will provide a flag for each suspected finding within this study. A preview image will be provided for each distinct suspected finding. BriefCase-Triage uses a foundation model-based artificial intelligence (AI) system to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images for each suspected finding that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical images and is not intended to be used as a diagnostic device. The results of BriefCase-Triage are intended to be used in conjunction with other patient information and based on their professional judgment to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.</p> | FDA indication is appropriate for consideration under the alternative pathway. |
| Newness Period                  | 510(k) clearance on 1/7/2026.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Newness date: 1/7/2026.                                                        |
| Cost Criterion                  | <p>Scenario 1: 3,747,413 claims mapping to 755 MS-DRGs, with 11.05 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV &gt;96 Hours with MCC).</p> <p>Scenario 2: 3,307,953 claims mapping to 749 MS-DRGs, with 12.18 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV &gt;96 Hours with MCC)</p> <p>Final inflated average case-weighted standardized charge per case (Scenario 1 – \$101,272; Scenario 2 – \$103,615) exceeded the average case-weighted threshold amount (Scenario 1 – \$75,836; Scenario 2 – \$76,621).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Meets cost criterion.                                                          |
| Technology Cost                 | The technology is a subscription-based model, with annual fees varying according to hospital bed size. Each hospital would be charged \$1,210 per bed. To calculate an average cost per case, the applicant did an analysis using total estimated subscription fees from all IPPS hospitals and divided by expected stays when the technology would be used by that hospital. Taking the average cost per case associated with inpatient stays across all hospitals identified, the applicant calculated an average cost per patient of \$211.59.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Maximum new technology add-on payment: \$137.53                                |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that BriefCase-Triage meets the cost criterion and are therefore proposing to approve BriefCase-Triage for new technology add-on payments for FY 2027 for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table. We consider the beginning of the newness period to commence on January 7, 2026, the date on which BriefCase-Triage received FDA marketing authorization.

Based on preliminary cost information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case

involving the use of BriefCase-Triage would be \$137.53 for FY 2027 (that is, 65 percent of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether BriefCase-Triage meets the cost criterion and our proposal to approve new technology add-on payments for BriefCase-Triage: CARE Multi-Triage CT Body for FY 2027.

#### 3. CARA System

Cara Medical submitted a FY 2027 application for new technology add-on payments for the CARA System. According to the applicant, the CARA

System software simulates the path of a patient's cardiac conduction system using anatomical landmarks identifiable on routine CT angiography (CTA) imaging to enable Conduction Guided Intervention (CGI). Per the applicant, CARA augmented fluoroscopy can be used to help the operator visualize, during the procedure, the proximity of his tools and device to the patient's conduction system.

The following table provides an overview of the new technology add-on payment application for the CARA System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251006TVQL6>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Preliminary CMS Assessment                                                                 |
|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | N/A                                                                                        |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> The Cara System is a medical device comprising two integrated functions:</p> <ol style="list-style-type: none"> <li>1. Cara Metis Simulator is a diagnostic imaging Software as a Medical Device (SaMD) product that identifies the personalized anatomical location of the cardiac conduction system derived from the patient's computed tomographic angiography (CTA).</li> <li>2. Cara Atlas Navigator is an imaging guidance system (hardware and software) that overlays the personalized anatomical location of the cardiac conduction system (generated by the CARA Metis Simulator) onto real-time, intra-procedural, fluoroscopic imaging to assist in fluoroscopic-guided interventional heart procedures.</li> </ol> <p>The Cara System is intended for preplanning and guidance of medical interventions in an area known to contain or be adjacent to the cardiac conduction system, such as percutaneous or surgical structural heart (SHD) procedures, including transcatheter aortic valve replacement (TVAR), transcatheter mitral valve replacement (TMVR), and transcatheter tricuspid valve replacement (TTVR), or in medical procedures where the physician desires to deliver therapy to the patient's cardiac conduction system or to a targeted location within it.</p> <p>Visualization of the patient's cardiac conduction system path can significantly reduce the risk of procedure related, iatrogenic cardiac conduction system disease with hemodynamic compromise (CDHC) following SHD procedures and can improve the effectiveness and outcomes of cardiac pacing procedures treating CDHC.</p> <p><b>FDA Indication:</b> Pending.</p> | Pending FDA marketing authorization.                                                       |
| <b>Newness Period</b>                  | Applicant anticipates FDA decision by May 1, 2026, consistent with its Breakthrough Device designation. No commercial availability delay expected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Pending FDA marketing authorization.                                                       |
| <b>Cost Criterion</b>                  | <p>145,429 claims mapping to 23 MS-DRGs, with 23.96 percent of claims mapping to MS-DRG 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC)</p> <p>Final inflated average case-weighted standardized charge per case (\$372,183) exceeded the average case-weighted threshold amount (\$180,548).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Meets cost criterion.                                                                      |
| <b>Technology Cost</b>                 | <p>The system is billed to hospitals on a per use basis, and costs vary depending on whether the procedure is an interventional procedure done in the catheterization lab with the CARA Atlas™ Navigator (\$10,500) and CARA Metis™ Simulator (\$7,000) for a total cost of \$17,500, or if it is a surgical procedure done in the operating room with the CARA Atlas™ Navigator (\$6,500) and CARA Metis™ Simulator (\$7,000) for a total cost of \$13,500, or if only CARA Metis™ Simulator (\$7,000) is used for procedural planning.</p> <p>The Cara Atlas™ Navigator is used for real-time, fluoroscopic overlay of the patient's conduction system during interventional procedures and for display of the original Metis™ pre-planning image with surgical landmarks in surgical procedures. The hardware for the CARA System is provided at no cost if the institution commits to purchase 100 total procedures.</p> <p>The applicant anticipates 90% of procedures will use both CARA Atlas™ Navigator and CARA Metis™ Simulator, and the market split between interventional to surgical application of CARA Atlas™ Navigator and CARA Metis™ Simulator will be 80% and 20%, respectively. The applicant anticipates 10% of procedures will only use CARA Metis™ Simulator. The applicant calculated a weighted average cost of \$15,700 per patient for the CARA System.</p>                                                                                                                                                                                                                                                                                                                                       | <p>Maximum new technology add-on payment: \$10,205.00</p> <p>See following discussion.</p> |

## BILLING CODE 4120-01-C

## Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the CARA

System meets the cost criterion and are therefore proposing to approve the CARA System for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing

authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

However, we question whether a surgical procedure done in the operating room with the CARA Atlas™ Navigator

would correspond to the FDA Breakthrough Device designated indication involving real-time, intra-procedural, fluoroscopic imaging to assist in fluoroscopic-guided interventional heart procedures. We would be interested in information clarifying the components and process for use of the CARA Atlas™ Navigator, accounting for the difference in cost between a surgical procedure and an interventional procedure. We also question whether procedures using only the CARA Metis™ Simulator would correspond to the FDA Breakthrough Device designated indication, as a medical device comprising two integrated functions (that is, integrated functions of both the CARA Metis™ Simulator and CARA Atlas™ Navigator). We note that under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-

on payment for FY 2027. We would be interested in detailed information clarifying the different uses of the CARA System components related to the Breakthrough Device designated indication. Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of the CARA System would be \$10,205.00 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the CARA System meets the cost criterion and our proposal to approve new technology add-on payments for the CARA System for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

#### 4. CERAMENT® V

BONESUPPORT Inc. submitted a FY 2027 application for new technology add-on payments for CERAMENT® V. According to the applicant, CERAMENT® V is a resorbable, vancomycin-eluting ceramic bone graft substitute intended for use as a bone void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis. Per the applicant, CERAMENT® V is indicated for use on vancomycin-sensitive microorganisms.

The following table provides an overview of the new technology add-on payment application for CERAMENT® V and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251006EFW54>.

BILLING CODE 4120-01-P

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Preliminary CMS Assessment                        |
|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | N/A                                               |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> CERAMENT® V is a resorbable, vancomycin-eluting ceramic bone graft substitute intended for use as a bone void filler as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis. By eluting vancomycin locally, CERAMENT® V can reduce the recurrence of osteomyelitis from vancomycin-sensitive microorganisms in order to protect bone healing. CERAMENT® V can augment provisional hardware to help support bone fragments during the surgical procedure. CERAMENT® V resorbs and is replaced by bone during the healing process while being protected from bacterial colonization by vancomycin.</p> <p><b>FDA Indication:</b> Pending.</p> | Pending FDA marketing authorization.              |
| <b>Newness Period</b>                  | Applicant anticipates FDA decision by May 1, 2026, consistent with its Breakthrough Device designation. Commercial availability delay expected for a few months.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Pending FDA marketing authorization.              |
| <b>Cost Criterion</b>                  | <p>13,079 claims mapping to 80 MS-DRGs, with 12.10 percent of claims mapping to MS-DRG 467 (Revision of Hip or Knee Replacement with CC).</p> <p>Final inflated average case-weighted standardized charge per case (\$171,702) exceeded the average case-weighted threshold amount (\$113,841).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Meets cost criterion.                             |
| <b>Technology Cost</b>                 | The amount used per patient depends on the complexity of injury, subsequent comorbidities, and location and size of the bone void, but an average patient will require ~ 10cc per procedure with an anticipated cost of \$8,750 for 10cc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Maximum new technology add-on payment: \$5,687.50 |

#### Newness Period

After review of the information provided by the applicant, we note that the applicant stated that the technology is not expected to be commercially available until a few months after FDA

marketing authorization because of the required time to implement the technical requirements to comply with FDA marketing authorization and to produce the first batches of CERAMENT® V for the United States. We are interested in additional

information regarding the anticipated cause for any delay in the technology's market availability, as another bone graft substitute from the applicant that was first approved for new technology add-on payment for FY 2023 (87 FR

48961 through 48966) did not have a delay in market availability.

#### Cost Criterion

We agree with the applicant that CERAMENT® V meets the cost criterion and are therefore proposing to approve CERAMENT® V for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of CERAMENT® V would be \$5,687.50 for

FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether CERAMENT® V meets the cost criterion and our proposal to approve new technology add-on payments for CERAMENT® V for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

#### 5. Ceribell Delirium Monitor System

Ceribell, Inc. submitted a FY 2027 application for new technology add-on

payments for the Ceribell Delirium Monitor System. According to the applicant, the Ceribell Delirium Monitor System is a medical device system comprised of proprietary software, signal acquisition headbands and a recorder. Per the applicant, the software utilizes a machine learning model to analyze EEG signals to detect features indicative of delirium.

The following table provides an overview of the new technology add-on payment application for the Ceribell Delirium Monitor System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251006WFMK2>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Preliminary CMS Assessment                     |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | XX20X89                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | See following discussion.                      |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> The Ceribell Delirium Monitor System is intended to analyze features associated with diffuse slowing electroencephalogram (EEG) patterns that may be indicative of delirium. The Ceribell Delirium Monitor System is intended to aid in the screening and monitoring of delirium with clinical assessments in adult patients aged 65 and older in critical care settings within hospitals.</p> <p><b>FDA Indication:</b> The Ceribell Delirium Monitor System is intended to analyze features associated with diffuse slowing electroencephalogram (EEG) patterns that may be indicative of delirium. The Ceribell Delirium Monitor software is intended to aid in the screening and monitoring of delirium with clinical assessments in adult patients in critical care settings within hospitals. The Ceribell Delirium Monitor System analyzes discrete segments of EEG to notify clinicians when EEG patterns associated with delirium are detected while monitoring the patient. Changes in patient condition that are detected by the device should be verified before commencing any interventions.</p> | See following discussion.                      |
| <b>Newness Period</b>                  | 510(k) clearance on 12/8/2025.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Newness date: 12/8/2025.                       |
| <b>Cost Criterion</b>                  | <p>Scenario 1: 2,448,833 claims mapping to 738 MS-DRGs, with 12 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV&gt;96 Hours with MCC)</p> <p>Scenario 2: 1,825,687 claims mapping to 732 MS-DRGs, with 16.08 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV&gt;96 Hours with MCC)</p> <p>Final inflated average case-weighted standardized charge per case (Scenario 1 - \$114,157; Scenario 2 - \$127,752) exceeded the average case-weighted threshold amount (Scenario 1 - \$95,951; Scenario 2 - \$95,038).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Meets cost criterion.                          |
| <b>Technology Cost</b>                 | <p>The total anticipated cost to the hospital is \$3,340 per patient, based on the \$799 operating costs of the Ceribell Delirium Monitor System Software and Headband which are packaged together and the anticipated weighted average length of stay of patients of 4.18 days (\$799 x 4.18 days = \$3,340). A new headband must be used for each day of monitoring due to technical considerations relating to usability and achieving optimal EEG signal quality. For example, each electrode of the headband contains a sealed packet of electroconductive gel which remains at optimal effectiveness for approximately one day once dispensed.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Maximum new technology add-on payment: \$2,171 |

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After review of the information provided by the applicant, we note that under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2027. As stated by the applicant, the FDA-cleared indication is different and is not limited to adult patients aged 65 and older, as noted in the Breakthrough Device designation. Therefore, only the use of the Ceribell Delirium Monitor System for patients aged 65 and older, and the FDA Breakthrough Device designation it received for that use, would be relevant for purposes of the new technology add-on payment application for FY 2027.

**ICD-10 Coding**

In addition, as noted by the applicant, the ICD-10-PCS procedure code XX20X89 (Monitoring of brain electrical activity, computer-aided detection and notification, new technology group 9) is used for a different technology (the Ceribell Status Epilepticus Monitor) to help diagnose status epilepticus, which is not the subject of this new technology add-on payment application. Therefore, the applicant has submitted a request for ICD-10-CM codes to differentiate use of the Ceribell Delirium Monitor System from use of the Ceribell Status Epilepticus Monitor, which was approved for new technology add-on payments for FY 2024 through FY 2026 (88 FR 58927 through 58930; 89 FR 70009; 90 FR 37260) and for which we are proposing to discontinue making new technology add-on payments for FY

2027 because it will no longer be considered new (as discussed in section II.E.4. of the preamble of this proposed rule).

Furthermore, for purposes of the new technology add-on payment, if approved, we believe it would be appropriate to exclude cases reporting the ICD-10-PCS procedure code XX20X89 in patients with status epilepticus, which would instead identify use of the Ceribell Status Epilepticus Monitor. Please see Table 10.2.— Ceribell Delirium Monitor System, associated with this proposed rule, for the list of ICD-10-CM diagnosis codes that we believe would identify patients with status epilepticus, which we propose to exclude from new technology add-on payment when reported in combination with ICD-10-PCS procedure code XX20X89.

We are inviting public comments on our proposal to exclude cases reporting these ICD-10-CM diagnosis codes in combination with the ICD-10-PCS procedure code XX20X89, for purposes of the new technology add-on payment for FY 2027, if approved.

**Cost Criterion**

We agree with the applicant that the Ceribell Delirium Monitor System meets the cost criterion and are therefore proposing to approve the Ceribell Delirium Monitor System for new technology add-on payments for FY 2027, for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table. We consider the beginning of the newness period to commence on December 8, 2025, the date on which the Ceribell Delirium Monitor System received FDA marketing authorization.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of the Ceribell Delirium Monitor System would be \$2,171 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the Ceribell Delirium Monitor System meets the cost criterion and our proposal to approve new technology add-on payments for the Ceribell Delirium Monitor System for FY 2027.

**6. CMORE® CT System (Posterior Cervico-Thoracic System)**

Icotec ag submitted a FY 2027 application for new technology add-on payments for the CMORE® CT System. According to the applicant, the CMORE® CT System is a posterior cervico-thoracic fixation system manufactured from BlackArmor® Carbon/PEEK material for standard posterior fixation of the spinal column which features a variety of screw sizes and types, as well as rod shapes, to accommodate patient anatomy.

The following table provides an overview of the new technology add-on payment application for the CMORE® CT System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP2510034V5CK>.

**BILLING CODE 4120-01-P**



|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Preliminary CMS Assessment                      |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | See following discussion.                       |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> The CMORE® CT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3): Traumatic spinal fractures and/or traumatic dislocations; Instability or deformity; Failed previous fusions (e.g. pseudarthrosis); Degenerative disease, including intractable radiculopathy and/or myelopathy; Neck and/or arm pain of discogenic origin as confirmed by radiographic studies; Degenerative disease of the facets with instability; Patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.</p> <p><b>FDA Indication:</b> The CMORE® CT System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In patients requiring adjuvant radiotherapy following spinal stabilization, metal markers at the screw tips can be used as fiducial markers in radiotherapy treatments (e.g., SBRT, proton therapy). The CMORE® CT System is intended to provide immobilization and stabilization of spinal segments with anterior interbody support implanted at the same spinal level/s as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3): Traumatic spinal fractures and/or traumatic dislocations; Instability or deformity; Failed previous fusions (e.g. pseudarthrosis); Degenerative disease, including intractable radiculopathy and/or myelopathy; Neck and/or arm pain of discogenic origin as confirmed by radiographic studies; Degenerative disease of the facets with instability; Patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression. The CMORE® CT System is intended to be used with anterior interbody support implanted at the same spinal level/s with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The CMORE® CT System may be connected to the VADER® Pedicle System using connectors.</p> | See following discussion.                       |
| <b>Newness Period</b>                  | <p>510(k) clearance on 11/12/2025.</p> <p>Commercial availability delay to 12/8/2025 – Applicant stated that this was the date on which the CMORE® CT System implants and instrument sets arrived at their U.S.-based logistics center, for sale in the U.S.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Newness date: 12/8/2025.                        |
| <b>Cost Criterion</b>                  | <p>48,900 claims mapping to 43 MS-DRGs, with 33 percent of claims mapping to MS-DRG 472 (Cervical Spinal Fusion with CC).</p> <p>Final inflated average case-weighted standardized charge per case (\$566.662) exceeded the average case-weighted threshold amount (\$167,312).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Meets cost criterion.                           |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital is \$93,700 for an average construction per patient. The applicant stated there are approximately 59 different components associated with the CMORE® CT System, all of which are operating costs, and the device cost per patient is a weighted average across multiple elements: Polyaxial Screws, Shank Screws, Rods (straight and curved), Nut Screws, Axial Connectors, and Parallel Connectors. An average construction for the CMORE® CT System utilizes: 10 Polyaxial or Shank Screws (\$79,500), 2 Rods (\$10,200), and 10 Locking/Nut screws (\$4,000).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Maximum new technology add-on payment: \$60,905 |

## BILLING CODE 4120-01-C

After review of the information provided by the applicant, we note that, as previously stated, under the

eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that

corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2027. The indication

for use for the CMORE® CT System in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, is not included in its Breakthrough Device designation. Therefore, the CMORE® CT System would only be eligible for new technology add-on payment for its Breakthrough Device-designated indication, as an adjunct to fusion of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3), if approved.

#### ICD-10 Coding

Please see Table 10.1.—CMORE® CT System, associated with this proposed rule, for the list of relevant ICD-10-PCS procedure codes that we believe would be appropriate to report in combination with use of the CMORE® CT System to identify use of the technology for the Breakthrough Device-designated indication, as an adjunct to fusion of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3). We are inviting public comments on the use of these ICD-10-PCS procedure codes to identify use of the technology for the Breakthrough Device-designated

indication for purposes of the new technology add-on payment, if approved.

#### Cost Criterion

We agree with the applicant that the CMORE® CT System meets the cost criterion and are therefore proposing to approve the CMORE® CT System for new technology add-on payments for FY 2027, for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table and as described previously. We consider the beginning of the newness period to commence on December 8, 2025, the date on which the CMORE® CT System became commercially available.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of the CMORE® CT System would be \$60,905 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the CMORE® CT System meets

the cost criterion and our proposal to approve new technology add-on payments for the CMORE® CT System for FY 2027.

#### 7. GORE® VIABAHN® FORTEGRA Venous Stent

W.L. Gore & Associates, Inc. submitted a FY 2027 application for new technology add-on payments for the GORE® VIABAHN® FORTEGRA Venous Stent. According to the applicant, the GORE® VIABAHN® FORTEGRA Venous Stent is an open-structure polymer lattice device providing intraluminal support in the inferior vena cava and, if clinically warranted, the common iliac veins, at the ilio caval confluence in patients with symptomatic vessel obstruction.

The following table provides an overview of the new technology add-on payment application for the GORE® VIABAHN® FORTEGRA Venous Stent and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251006MBT8G>.

BILLING CODE 4120-01-P

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                           | Preliminary CMS Assessment                                                     |
|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                             | N/A                                                                            |
| <b>Breakthrough Device Requirement</b> | <b>Breakthrough Device Designation Indication:</b> Indicated for treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.<br><br><b>FDA Indication:</b> This device is indicated for use in the treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.                                     | FDA indication is appropriate for consideration under the alternative pathway. |
| <b>Newness Period</b>                  | PMA approval on 12/19/2025                                                                                                                                                                                                                                                                                                                                                                     | Newness date: 12/19/2025.                                                      |
| <b>Cost Criterion</b>                  | 337 claims mapping to 25 MS-DRGs, with 11.87 percent of claims mapping to MS-DRG 270 (Other Major Cardiovascular Procedures with MCC).<br><br>Final inflated average case-weighted standardized charge per case (\$295,766) exceeded the average case-weighted threshold amount (\$136,998).                                                                                                   | Meets cost criterion.                                                          |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital is \$11,056 per patient. An average of 5.12 stents were used per case (1.15 large diameter and 3.97 small diameter stents) based on clinical trial (VNS-21-05). Per the applicant, large diameter stent cost per component is \$3,400 (\$3,400 x 1.15 = \$3,910) and small diameter stent cost per component is \$1,800 (\$1,800 x 3.97 = \$7,146). | Maximum new technology add-on payment: \$7,186.40                              |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the GORE® VIABAHN® FORTEGRA Venous Stent meets the cost criterion and are therefore proposing to approve the GORE® VIABAHN® FORTEGRA Venous

Stent for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table. We consider the beginning of the newness period to commence on December 19, 2025, the date on which the GORE® VIABAHN® FORTEGRA

Venous Stent received FDA marketing authorization.

Based on preliminary cost information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of the GORE® VIABAHN® Venous Stent would be

\$7,186.40 for FY 2027 (that is, 65 percent of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the GORE® VIABAHN® Venous Stent meets the cost criterion and our proposal to approve new technology add-on payments for the GORE® VIABAHN® Venous Stent for FY 2027.

#### 8. Infuse™ Bone Graft

Medtronic Sofamor Danek USA, Inc. submitted a FY 2027 application for new technology add-on payments for Infuse™ Bone Graft. According to the applicant, Infuse™ Bone Graft is a bone graft material designed to promote bone formation at the site of implantation for transforaminal lumbar interbody fusion (TLIF), at one or two adjacent levels from L2–S1 in the treatment of degenerative disc disease (DDD). Per the applicant, it consists of two primary

components, recombinant human bone morphogenetic protein-2 (rhBMP-2) and an absorbable collagen sponge which serves as a delivery matrix and scaffold for bone growth.

The following table provides an overview of the new technology add-on payment application for Infuse™ Bone Graft and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP250929NNTp8>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Preliminary CMS Assessment                                                     |
|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | See following discussion.                                                      |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> Infuse™ Bone Graft with an intervertebral body fusion device and a commercially available Medtronic metallic screw and rod system is intended for use in a transforaminal lumbar interbody fusion (TLIF) surgical approach at one or two adjacent levels from L2–S1 in the treatment of degenerative disease of the lumbosacral spine.</p> <p><b>FDA Indication:</b> Infuse™ Bone Graft with an FDA cleared intervertebral body fusion device and metallic screw-and-rod system is indicated for use in a transforaminal lumbar interbody fusion (TLIF) surgical approach at one or two adjacent levels from L2–S1 in the treatment of symptomatic degenerative disc disease (DDD) confirmed by patient history and radiographic studies and having at least six months of nonoperative treatment attempted prior to treatment with Infuse™ Bone Graft.</p> | FDA indication is appropriate for consideration under the alternative pathway. |
| <b>Newness Period</b>                  | PMA approval on 2/13/2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Newness date: 2/13/2026.                                                       |
| <b>Cost Criterion</b>                  | <p>Scenarios 1 and 2:<br/>4,475 claims mapping to 4 MS-DRGs with 58.73 percent of claims mapping to MS-DRG 451 (Single Level Spinal Fusion Except Cervical without MCC).</p> <p>Scenario 3:<br/>2,771 claims mapping to 2 MS-DRGs with 94.84 percent of claims mapping to 451 (Single Level Spinal Fusion Except Cervical without MCC).</p> <p>Final inflated average case-weighted standardized charge per case (Scenario 1 – \$218,383; Scenario 2 – \$195,608; Scenario 3 – \$194,873) exceeded the average case-weighted threshold amount (Scenarios 1 and 2 – \$147,656; Scenario 3 – \$135,414).</p>                                                                                                                                                                                                                                                                                                        | Meets cost criterion.                                                          |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital is \$6,764 per patient, which is the cost of an Infuse™ Bone Graft Medium kit. There are several kit sizes available with different amounts of rhBMP-2 which a hospital may use in 1- or 2-level TLIF procedures (range: XX Small kit at 1.05mg to Large kit at 12mg). The Medium kit provides 8.4mg of rhBMP-2. The applicant expects that inpatient cases among Medicare beneficiaries will be clinically complex and will commonly receive a 2-level fusion with Infuse™ Bone Graft at 4.2mg per level.                                                                                                                                                                                                                                                                                                                                                             | Maximum new technology add-on payment: \$4,396.60                              |

#### ICD-10 Coding

After review of the information provided by the applicant, we note that Infuse™ Bone Graft has been granted other FDA approvals beyond the scope of its Breakthrough Device designation.

We believe the relevant ICD-10-PCS procedure codes that would be appropriate to report in combination with use of Infuse™ Bone Graft, to identify use of the technology for the Breakthrough Device-designated indication in a TLIF surgical approach

at one or two adjacent levels from L2–S1 in the treatment of degenerative disease of the lumbosacral spine for purposes of the new technology add-on payment, if approved, would be the following codes:

| ICD-10-PCS Code | Description                                                                                                                               |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| 0SG00AJ         | Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach                         |
| 0SG03AJ         | Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach                 |
| 0SG04AJ         | Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach      |
| 0SG10AJ         | Fusion of lumbar vertebral joints, 2 or more with interbody fusion device, posterior approach, anterior column, open                      |
| 0SG13AJ         | Fusion of lumbar vertebral joints, 2 or more with interbody fusion device, posterior approach, anterior column, percutaneous              |
| 0SG14AJ         | Fusion of lumbar vertebral joints, 2 or more with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic   |
| 0SG30AJ         | Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, open approach                    |
| 0SG33AJ         | Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach            |
| 0SG34AJ         | Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach |

We are inviting public comments on the use of these ICD-10-PCS procedure codes to identify use of the technology for the Breakthrough Device-designated indication for purposes of the new technology add-on payment, if approved.

#### Cost Criterion

We agree with the applicant that Infuse™ Bone Graft meets the cost criterion and are therefore proposing to approve Infuse™ Bone Graft for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table and as described previously. We consider the beginning of the newness period to commence on February 13, 2026, the date on which Infuse™ Bone Graft received FDA marketing authorization.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of Infuse™ Bone Graft would be \$4,396.60 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether Infuse™ Bone Graft meets the cost criterion and our proposal to approve new technology add-on payments for Infuse™ Bone Graft for FY 2027.

9. InVision Precision Cardiac Amyloid Invision Medical Technology submitted a FY 2027 application for

new technology add-on payments for InVision Precision Cardiac Amyloid (InVision PCA). According to the applicant, InVision PCA is a SaMD machine-learning disease detection algorithm to identify high suspicion of cardiac amyloidosis from routinely obtained echocardiogram videos. Per the applicant, the device assists clinicians in the diagnosis of cardiac amyloidosis.

The following table provides an overview of the new technology add-on payment application for InVision PCA and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251002J7D89>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Preliminary CMS Assessment                                                     |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | N/A                                                                            |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> InVision Precision Cardiac Amyloidosis Screening is intended to process transthoracic cardiac ultrasound images to aid clinicians with identification of patients at high risk for cardiac amyloidosis from echocardiogram videos. This measurement can be used to assist the clinician in identifying patients that would benefit from downstream cardiac evaluation and testing. The device is intended for adult population of 22 years or older.</p> <p><b>FDA Indication:</b> InVision Precision Cardiac Amyloid is a machine learning-based decision support system indicated as a screening tool for adult patients aged 65 years and over undergoing cardiovascular assessment using echocardiography. When utilized by an interpreting physician, this device provides information alerting the physician for referral to confirmatory investigations. InVision Precision Cardiac Amyloid is indicated in adult populations over 65 years of age. Patient management decisions should not be made solely on the results of the InVision Precision Cardiac Amyloid.</p> | FDA indication is appropriate for consideration under the alternative pathway. |
| <b>Newness Period</b>                  | 510(k) clearance on 5/21/2025.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Newness date: 5/21/2025.                                                       |
| <b>Cost Criterion</b>                  | <p>80,241 claims mapping to 643 MS-DRGs, with none exceeding more than 10 percent of the total identified cases.</p> <p>Final inflated average case-weighted standardized charge per case (\$129,789) exceeded the average case-weighted threshold amount (\$97,126).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Meets cost criterion.                                                          |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital is \$250 per patient.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Maximum new technology add-on payment: \$162.50                                |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that InVision PCA meets the cost criterion and are therefore proposing to approve InVision PCA for new technology add-on payments for FY 2027, for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table. We consider the beginning of the newness period to commence on May 21, 2025, the date on which InVision PCA received FDA market authorization.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of InVision PCA would be \$162.50 for FY 2027 (that is, 65 percent of the average

cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether InVision PCA meets the cost criterion and our proposal to approve new technology add-on payments for InVision PCA for FY 2027.

#### 10. MediBeacon® Transdermal GFR Measurement System (TGFR)

MediBeacon submitted a FY 2027 application for new technology add-on payments for the MediBeacon® Transdermal GFR Measurement System (MediBeacon® TGFR). According to the applicant, the MediBeacon® TGFR provides an assessment of glomerular filtration rate (GFR) at the point of care and employs an intravenously administered fluorescent tracer agent

which has been engineered to be excreted exclusively by the kidneys. Per the applicant, noninvasive transdermal fluorescence detection of the excretion rate of the agent is converted into a GFR reading. We note that the applicant submitted an application for new technology add-on payments for this technology for FY 2025 (89 FR 36128 through FR 36130; 89 FR 69204) and FY 2024 (88 FR 26954 through 26955; 88 FR 58919) under the name Transdermal GFR Measurement System Utilizing Lumitrace.

The following table provides an overview of the new technology add-on payment application for the MediBeacon® TGFR and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251003G1JT8>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                  | Preliminary CMS Assessment                     |
|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | XT25XE5                                                                                                                                                                                                                                                               | No concerns.                                   |
| <b>Breakthrough Device Requirement</b> | <b>Breakthrough Device Designation Indication:</b> The Transdermal GFR Measurement System is intended to measure Glomerular Filtration Rate (GFR) in patients with impaired or normal renal function.<br><b>FDA Indication:</b> Pending.                              | Pending FDA marketing authorization.           |
| <b>Newness Period</b>                  | Applicant anticipates FDA decision by May 1, 2026, consistent with its Breakthrough Device designation.<br>No commercial availability delay expected.                                                                                                                 | Pending FDA marketing authorization.           |
| <b>Cost Criterion</b>                  | 837,310 claims mapping to 109 MS-DRGs, with 7.22 percent of claims mapping to MS-DRG 683 (Renal Failure with CC)<br><br>Final inflated average case-weighted standardized charge per case (\$107,522) exceeded the average case-weighted threshold amount (\$95,979). | Meets cost criterion.                          |
| <b>Technology Cost</b>                 | The applicant has not provided an estimate for the cost of the MediBeacon® TGFR at the time of this proposed rule.                                                                                                                                                    | Pending cost.<br><br>See following discussion. |

**BILLING CODE 4120-01-C****Cost Criterion**

After review of the information provided by the applicant, we agree with the applicant that the MediBeacon® TGFR meets the cost criterion and are therefore proposing to approve the MediBeacon® TGFR for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

The applicant has not provided an estimate for the cost of the MediBeacon® TGFR at the time of this proposed rule. The applicant stated that there would be four components for the cost of the technology: the operating cost of Lumitrace®, the operating cost of the TGFR Reusable Sensor, the operating cost of the TGFR Adhesive Ring and the capital cost of the TGFR Monitor. Because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, we

do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). Therefore, it appears that the TGFR Monitor component is not eligible for new technology add-on payment because, as discussed in prior rulemaking, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). We would be interested in additional information about the TGFR Reusable Sensor, which also appears to be a reusable, capital expenditure. We expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for the MediBeacon® TGFR would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS-DRG payment for the case.

We invite public comments on whether the MediBeacon® TGFR meets the cost criterion and our proposal to approve new technology add-on

payments for the MediBeacon® Transdermal GFR Measurement System for FY 2027, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

#### 11. Micro Medical Solutions MicroStent and the MicroStent XL Peripheral Vascular Stent System

Micro Medical Solutions, Inc. submitted a FY 2027 application for new technology add-on payments for the Micro Medical Solutions MicroStent and the MicroStent XL Peripheral Vascular Stent System (MicroStent). According to the applicant, the MicroStent is a self-expanding nitinol stent system for permanent implantation to improve luminal diameter in the treatment of ischemia in the lower leg.

The following table provides an overview of the new technology add-on payment application for the MicroStent and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251002M8X4j>.

**BILLING CODE 4120-01-P**

|                                        | Applicant Statements                                                                                                                                                                                                                                                                       | Preliminary CMS Assessment                     |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                         | N/A                                            |
| <b>Breakthrough Device Requirement</b> | <b>Breakthrough Device Designation Indication:</b> The MicroStent Peripheral Stent System is intended to improve luminal diameter in the treatment of ischemia in the lower leg with reference vessel diameters ranging from 2.5 mm - 4.5 mm.<br><br><b>FDA Indication:</b> Pending.       | Pending FDA marketing authorization.           |
| <b>Newness Period</b>                  | Applicant anticipates FDA decision by May 1, 2026, consistent with its Breakthrough Device designation.<br>No commercial availability delay expected.                                                                                                                                      | Pending FDA marketing authorization.           |
| <b>Cost Criterion</b>                  | 2,665 claims mapping to 75 MS-DRGs, with 17 percent of claims mapping to MS-DRG 271 (Other Major Cardiovascular Procedures with CC).<br><br>Final inflated average case-weighted standardized charge per case (\$273,581) exceeded the average case-weighted threshold amount (\$140,905). | Meets cost criterion.                          |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital is \$7,000 per patient. The applicant stated that the cost of the MicroStent System is \$3,500 and an average of two systems will be required per patient.                                                                                      | Maximum new technology add-on payment: \$4,550 |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the MicroStent meets the cost criterion and are therefore proposing to approve the MicroStent for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

Based on preliminary cost information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of the MicroStent would be \$4,550 for FY 2027 (that is, 65 percent of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on

revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the MicroStent meets the cost criterion and our proposal to approve new technology add-on payments for the Micro Medical Solutions MicroStent and the MicroStent XL Peripheral Vascular Stent System for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

#### 12. Nelli™ Seizure Monitoring System

Neuro Event Labs submitted a FY 2027 application for new technology add-on payments for the Nelli™ Seizure Monitoring System. According to the applicant, the Nelli™ Seizure Monitoring System is a prescription-only device that is designed to be used

as an adjunct to seizure monitoring in healthcare facilities during periods of rest. Per the applicant, the device utilizes automated analysis of audio and video (media) to identify epileptic and non-epileptic seizure events with a positive motor component. We note that the applicant submitted an application for new technology add-on payments for this technology for FY 2026 (90 FR 18189 through 18191; 90 FR 36770), FY2024 (88 FR 26940 through 26942; 88 FR 58919), and FY 2023 (87 FR 28341 through 28342; 87 FR 48960).

The following table provides an overview of the new technology add-on payment application for the Nelli™ Seizure Monitoring System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP2509294WQJJ>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Preliminary CMS Assessment                                                           |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | XXE0X48                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | No concerns.                                                                         |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> Nelli software is intended for the automated analysis of audio and video data to identify seizure events with a positive motor component in children and adults. The software provides objective summaries of semiological components of identified events (including velocity and acceleration of movements, seizure frequency, seizure duration, heart rate, and respiratory rate). Nelli software provides A/V data for physicians to characterize seizures and peri-ictal events.</p> <p><b>FDA Indication:</b> Nelli is indicated for use as an adjunct to seizure monitoring of patients aged 18 years and above in healthcare facilities during periods of rest. The device utilizes automated analysis of audio and video (media) to identify epileptic and non-epileptic seizure events with a positive motor component. The system provides prioritization of identified major seizures and other motor events for review and media playback by a qualified healthcare professional.</p> | FDA indication is appropriate for consideration under the alternative pathway.       |
| <b>Newness Period</b>                  | 510(k) clearance on November 21, 2025.<br>Commercial availability delay until January 20, 2026 - Applicant stated that the company needed to set up its distribution operations in the U.S., and the technology became available for use by hospitals on this date.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Newness date: 1/20/2026.                                                             |
| <b>Cost Criterion</b>                  | <p><b>Scenario 1:</b><br/>13,347 claims mapping to 19 MS-DRGs, with 53.85 percent of claims mapping to MS-DRG 101 (Seizures without MCC).</p> <p><b>Scenario 2:</b><br/>26,833 claims mapping to 19 MS-DRGs, with 34.25 percent of claims mapping to MS-DRG 101 (Seizures without MCC).</p> <p>Final inflated average case-weighted standardized charge per case (Scenario 1 – \$91,096; Scenario 2 – \$129,564) exceeded the average case-weighted threshold amount (Scenario 1 – \$63,676; Scenario 2 – \$72,384).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Meets cost criterion.                                                                |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital is \$1,589 per patient which includes one-time real time AI analysis during inpatient hospital stay at \$1,500 and a capital cost of \$89. The \$89 capital cost is based on the \$2,500 cost of the Nelli® Personal Recording Unit (PRU) with camera and microphone, 5 year depreciation of capital, an average of 10 devices per hospital, and an average 56 patients using the device per year per hospital.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <p>Maximum new technology add-on payment: \$975</p> <p>See following discussion.</p> |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the Nelli™ Seizure Monitoring System meets the cost criterion and are therefore proposing to approve the Nelli™ Seizure Monitoring System for new technology add-on payments for FY 2027, for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table. We consider the beginning of the newness period to commence on January 20, 2026, the date on which the Nelli™ Seizure Monitoring System became commercially available.

As previously noted, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). As noted, the applicant included capital

costs of \$89 for the PRU in the total technology cost. Therefore, as it appears that these costs are not eligible for new technology add-on payment, we note that any new technology add-on payment for the Nelli™ Seizure Monitoring System would be based on only the operating costs of \$1,500 for the analysis during inpatient hospital stay. As a result, based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of the Nelli™ Seizure Monitoring System would be \$975 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the Nelli™ Seizure Monitoring

System meets the cost criterion and our proposal to approve new technology add-on payments for the Nelli™ Seizure Monitoring System for FY 2027.

#### 13. NEXUS® Aortic Arch Stent Graft System

ENDOSPAN submitted a FY 2027 application for new technology add-on payments for the NEXUS® Aortic Arch Stent Graft System. According to the applicant, the NEXUS® Aortic Arch Stent Graft System is a branched endovascular stent graft system designed specifically for repair of aortic arch pathologies (including aneurysms, chronic dissections, penetrating ulcers, and intramural hematoma) involving Zone 0 ascending aorta and the arch.

The following table provides an overview of the new technology add-on payment application for the NEXUS® Aortic Arch Stent Graft System and CMS's preliminary assessment. For



additional details provided by the applicant, please refer to the online application posting at [https://](https://mearis.cms.gov/public/publications/ntap/NTP251006114Y0)

[mearis.cms.gov/public/publications/ntap/NTP251006114Y0](https://mearis.cms.gov/public/publications/ntap/NTP251006114Y0).

|                                 | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Preliminary CMS Assessment                      |
|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Unique ICD-10-PCS Code(s)?      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | N/A                                             |
| Breakthrough Device Requirement | <b>Breakthrough Device Designation Indication:</b> The NEXUS™ Aortic Arch Stent Graft System is indicated for the endovascular treatment of thoracic aortic lesions involving the aortic arch including chronic dissections, aneurysms, penetrating aortic ulcers and intramural hematoma, with a proximal landing zone in the ascending aorta and in the brachiocephalic artery. The NEXUS™ Aortic Arch Stent Graft System is indicated for exclusion of the aneurysm or the false lumen and the restoration of blood flow through the stent graft lumen. Patients should have appropriate anatomy to accommodate the NEXUS System in an endovascular procedure.<br><br><b>FDA Indication:</b> Pending. | Pending FDA marketing authorization.            |
| Newness Period                  | Applicant anticipates FDA decision by May 1, 2026, consistent with its Breakthrough Device designation.<br>No commercial availability delay expected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Pending FDA marketing authorization.            |
| Cost Criterion                  | 1,219 claims mapping to 16 MS-DRGs, with 33.72 percent of claims mapping to MS-DRG 220 (Cardiac Valve and Other Major Cardiothoracic Procedure with and without Cardiac Catheterization with CC).<br><br>Final inflated average case-weighted standardized charge per case (\$513,444) exceeded the average case-weighted threshold amount (\$257,842).                                                                                                                                                                                                                                                                                                                                                  | Meets cost criterion.                           |
| Technology Cost                 | The total anticipated cost to the hospital is \$55,200 per patient. Per the applicant, the arch stent graft and ascending curve aorta stent graft are \$45,000 per patient and will be used in every procedure. The descending extension stent graft is \$17,000 per patient but is only used in 60 percent of the procedures based on clinical trial data (\$17,000 x .60 = \$10,200).                                                                                                                                                                                                                                                                                                                  | Maximum new technology add-on payment: \$35,880 |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the NEXUS® Aortic Arch Stent Graft System meets the cost criterion and are therefore proposing to approve the NEXUS® Aortic Arch Stent Graft System for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

Based on preliminary cost information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of the NEXUS® Aortic Arch Stent Graft System would be \$35,880 for FY 2027 (that is, 65 percent

of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the NEXUS® Aortic Arch Stent Graft System meets the cost criterion and our proposal to approve new technology add-on payments for the NEXUS® Aortic Arch Stent Graft System for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

#### 14. OmniaSecure™ MRI SureScan™ Lead Model 3930M

Medtronic submitted a FY 2027 application for new technology add-on

payments for the OmniaSecure™ MRI SureScan™ Lead Model 3930M (OmniaSecure™ defibrillation lead). According to the applicant, the OmniaSecure™ defibrillation lead is an implantable defibrillation lead designed to deliver pacing, sensing, cardioversion, and defibrillation therapy for patients at risk of life-threatening ventricular arrhythmias.

The following table provides an overview of the new technology add-on payment application for the OmniaSecure™ defibrillation lead and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP250930Q7TFH>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Preliminary CMS Assessment                                                     |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | N/A                                                                            |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> The Model 3930M lead is intended for use in the right ventricle for sensing, pacing, cardioversion, and defibrillation when a cardiac implantable electronic device is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening tachyarrhythmias. This includes adolescent pediatric patients who are at least 30 kg and are also at least 12 years of age, and whose cardiac anatomy is conducive to RV coil placement.</p> <p><b>FDA Indication:</b> This device is indicated for single use in the right ventricle for pacing, sensing, cardioversion, and defibrillation when a cardiac implantable electronic device is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias. This includes adolescent pediatric patients who are at least 30 kg and are also at least 12 years of age, and whose cardiac anatomy is conducive to RV coil placement.</p> | FDA indication is appropriate for consideration under the alternative pathway. |
| <b>Newness Period</b>                  | PMA approved on 4/22/2025<br>Commercial availability delay until 1/7/2026, due to field sales training and contracting with hospitals prior to market availability in the U.S.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Newness date: 1/7/2026.                                                        |
| <b>Cost Criterion</b>                  | 9,809 claims mapping to 4 MS-DRGs, with 35.80 percent of claims mapping to MS-DRG 277 (Cardiac Defibrillator Implant without MCC)<br><br>Final inflated average case-weighted standardized charge per case (\$256,251) exceeded the average case-weighted threshold amount (\$238,636).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Meets cost criterion.                                                          |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital is \$11,995 per patient, for one OmniaSecure™ defibrillation lead.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Maximum new technology add-on payment: \$7,796.75                              |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the OmniaSecure™ defibrillation lead meets the cost criterion and are therefore proposing to approve the OmniaSecure™ defibrillation lead for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table. We consider the beginning of the newness period to commence on January 7, 2026, the date on which the OmniaSecure™ defibrillation lead became commercially available.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of the OmniaSecure™ defibrillation lead

would be \$7,796.75 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the OmniaSecure™ defibrillation lead meets the cost criterion and our proposal to approve new technology add-on payments for the OmniaSecure™ MRI SureScan™ Lead Model 3930M for FY 2027.

#### 15. PearlMatrix™ P-15 Peptide Enhanced Bone Graft

Cerapedics, Inc. submitted a FY 2027 application for new technology add-on payments for PearlMatrix™ P-15 Peptide Enhanced Bone Graft. According to the applicant, PearlMatrix™ P-15 Peptide Enhanced

Bone Graft is a composite bone graft material consisting of a synthetic peptide, found naturally occurring in human Type I collagen (P-15), adsorbed onto calcium phosphate particles, which are incorporated into a fibrous collagen matrix putty as an inert carrier. We note that the applicant submitted an application for new technology add-on payments for this technology for FY 2026 (90 FR 18193 through 18195; 90 FR 36770).

The following table provides an overview of the new technology add-on payment application for PearlMatrix™ P-15 Peptide Enhanced Bone Graft and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251001VFM4K>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Preliminary CMS Assessment                                                                                             |
|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | XW0U0XB, XW0U3XB, or XW0U4XB                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | See following discussion.                                                                                              |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> The P-15L Bone Graft is indicated for intervertebral body fusion of the spine in skeletally mature patients. The P-15L Bone Graft is intended to be used in conjunction with a TLIF Fusion Device and supplemental internal spinal fixation systems cleared by the FDA for use in the lumbosacral spine. The system is to be used in patients who have had at least six months of non-operative treatment. The P-15L Bone Graft is intended for use at one level in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.</p> <p><b>FDA Indication:</b> This device is indicated for intervertebral body fusion of the spine in skeletally mature patients. PearlMatrix™ Bone Graft is intended to be used in conjunction with a PEEK TLIF Fusion Device and supplemental internal spinal fixation systems cleared by the FDA for use in the lumbosacral spine. The system is to be used in patients who have had at least six months of non-operative treatment. PearlMatrix™ Bone Graft is intended for use at one level in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back and/or radicular pain of discogenic origin with degeneration of the disc confirmed by history, physical exam, and radiographic studies.</p> <p>Per the applicant, the P-15L Bone Graft named in the Breakthrough Device designation letter is the same device as PearlMatrix™ P-15 Peptide Enhanced Bone Graft.</p> | <p>FDA indication is appropriate for consideration under the alternative pathway.</p> <p>See following discussion.</p> |
| <b>Newness Period</b>                  | PMA approval on 6/18/2025                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Newness date: 6/18/2025.                                                                                               |
| <b>Cost Criterion</b>                  | <p>6,211 claims mapping to 2 MS-DRGs, with 94.85 percent of claims mapping to MS-DRG 451 (Single Level Spinal Fusion Except Cervical without MCC).</p> <p>Final inflated average case-weighted standardized charge per case (\$158,116) exceeded the average case-weighted threshold amount (\$135,408).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Meets cost criterion.                                                                                                  |
| <b>Technology Cost</b>                 | An average of one (10 cc) kit is used per inpatient stay, based on the average number of units per inpatient stay (8.2) in clinical trial. The total anticipated cost to the hospital is \$6,500 per patient, per kit. The applicant provided the following cost breakdown of each component: bone graft peptide (\$3,120 operating cost and \$780 capital cost), porcine anorganic bone mineral (\$780 operating cost and \$195 capital cost), and fibrous collagen matrix (\$1,300 operating cost and \$325 capital cost).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>Maximum new technology add-on payment: \$3,380</p> <p>See following discussion.</p>                                 |

#### ICD-10-CM Coding

After review of the information provided by the applicant, we note that subsequent to the June 18, 2025 PMA as listed in the table, a supplemental PMA for PearlMatrix™ P-15 Peptide Enhanced Bone Graft was approved on December 11, 2025,<sup>81</sup> expanding the indication to allow implantation of the product using additional surgical approaches. As previously stated, under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's

Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2027. Therefore, it appears that only the use of the PearlMatrix™ P-15 Peptide Enhanced Bone Graft in conjunction with a TLIF device, and the FDA Breakthrough Device designation it received for that use, would be relevant for purposes of the new technology add-on payment application for FY 2027. The applicant stated that effective October 1, 2025, the following ICD-10-PCS codes could be used to uniquely describe procedures involving the use of the technology: XW0U0XB (Introduction of peptide enhanced bone void filler into joints,

open approach, new technology group 11), XW0U3XB (Introduction of peptide enhanced bone void filler into joints, percutaneous approach, new technology group 11), or XW0U4XB (Introduction of peptide enhanced bone void filler into joints, percutaneous endoscopic approach, new technology group 11). We believe the relevant ICD-10-PCS procedure codes that would be appropriate to report in combination with the PearlMatrix™ P-15 Peptide Enhanced Bone Graft's unique ICD-10-PCS codes to identify use of the technology for the Breakthrough Device-designated indication would be the following:

<sup>81</sup> <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P240001S001>.

| ICD-10-PCS Code | Description                                                                                                                               |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| 0SG00AJ         | Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach                         |
| 0SG03AJ         | Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach                 |
| 0SG04AJ         | Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach      |
| 0SG30AJ         | Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, open approach                    |
| 0SG33AJ         | Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach            |
| 0SG34AJ         | Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach |

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We are inviting public comments on the use of these ICD-10-PCS procedure codes to identify use of the technology for the Breakthrough Device-designated indication for purposes of the new technology add-on payment, if approved.

**Cost Criterion**

We agree with the applicant that PearlMatrix™ P-15 Peptide Enhanced Bone Graft meets the cost criterion and are therefore proposing to approve PearlMatrix™ P-15 Peptide Enhanced Bone Graft for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table and as described previously. We consider the beginning of the newness period to commence on June 18, 2025, the date on which PearlMatrix™ P-15 Peptide Enhanced Bone Graft received FDA marketing authorization.

Based on preliminary cost information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of PearlMatrix™ P-15 Peptide Enhanced Bone Graft to the hospital to be \$6,500 per patient, for one 10 cc kit used per

inpatient stay. As the applicant stated, there are capital costs of \$1,300 for the bone graft peptide, porcine anorganic bone mineral, and fibrous collagen matrix. As previously discussed, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). Therefore, as it appears that the \$1300 capital costs are not eligible for new technology add-on payment, we note that any new technology add-on payment for PearlMatrix P-15 Peptide Enhanced Bone Graft would be based on only the operating costs of \$5,200 for the bone graft peptide, porcine anorganic bone mineral, and fibrous collagen matrix. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of PearlMatrix™ P-15 Peptide Enhanced Bone Graft would be \$3,380 for FY 2027 (that is, 65 percent of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether PearlMatrix™ P-15 Peptide

Enhanced Bone Graft meets the cost criterion and our proposal to approve new technology add-on payments for PearlMatrix™ P-15 Peptide Enhanced Bone Graft for FY 2027.

**16. PMcardio® STEMI AI ECG Model**

Powerful Medical Inc. submitted a FY 2027 application for new technology add-on payments for the PMcardio® STEMI AI ECG Model (PMcardio® STEMI AI). According to the applicant, PMcardio® STEMI AI is a stand-alone software device intended to analyze resting 12-lead ECGs of patients presenting with symptoms suspicious for acute coronary syndromes in the hospital setting. Per the applicant, the technology identifies ECG patterns of STEMI/STEMI-equivalents as an adjunctive decision support tool used by healthcare professionals.

The following table provides an overview of the new technology add-on payment application for PMcardio® STEMI AI and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251006/RE0P>.

**BILLING CODE 4120-01-P**

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Preliminary CMS Assessment                      |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | N/A                                             |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> The STEMI AI ECG Model is a stand-alone software device (SaMD) intended for the analysis of resting 12-lead ECGs of adult patients presenting with symptoms suspicious for acute coronary syndrome (chest pain or perceived anginal equivalent such as shortness of breath and epigastric pain) in the triage setting of such patients (e.g., ED or EMS). The STEMI AI ECG Model identifies ECG patterns of STEMI and STEMI-equivalents on 12-lead ECGs as an adjunctive decision support tool used by trained first-line healthcare professionals (non-cardiologists). The device is intended to be used in conjunction with the standard of care in ED and EMS settings to improve the prioritization of patients with STEMI or STEMI-equivalents with an automated timely notification to a cardiologist for a full patient evaluation. The device is not intended to replace a health care professional's ECG interpretation and a negative result from the STEMI AI ECG Model should not override a healthcare professional's assessment that the ECG is consistent with STEMI or STEMI equivalent. No therapeutic decisions should be made based solely on the STEMI AI ECG Model output.</p> <p><b>FDA Indication:</b> Pending.</p> | Pending FDA marketing authorization.            |
| <b>Newness Period</b>                  | Applicant anticipates FDA decision by May 1, 2026, consistent with its Breakthrough Device designation.<br>No commercial availability delay expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Pending FDA marketing authorization.            |
| <b>Cost Criterion</b>                  | <p>194,764 claims mapping to 76 MS-DRGs, with 18.55 percent of claims mapping to MS-DRG 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device without MCC).</p> <p>Final inflated average case-weighted standardized charge per case (\$125,859) exceeded the average case-weighted threshold amount (\$108,547).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Meets cost criterion.                           |
| <b>Technology Cost</b>                 | The total annual licensing cost to the hospital will reflect a per patient, per analysis cost of \$175 per patient. Per the applicant, at this time, the STEMI AI-ECG Model is not commercially available and therefore the cost of the technology was calculated based on expected utilization across all IPPS hospitals and not on current subscribing hospitals, as there are none at this time.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Maximum new technology add-on payment: \$113.75 |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that PMcardio® STEMI AI meets the cost criterion and are therefore proposing to approve PMcardio® STEMI AI for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of PMcardio® STEMI AI would be \$113.75 for FY 2027 (that is, 65% of the average

cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether PMcardio® STEMI AI meets the cost criterion and our proposal to approve new technology add-on payments for the PMcardio® STEMI AI ECG Model for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

#### 17. SAPIEN M3 Transcatheter Mitral Valve Replacement System

Edwards LifeSciences, LLC submitted a FY 2027 application for new

technology add-on payments for the SAPIEN M3 Transcatheter Mitral Valve Replacement System (the SAPIEN M3 TMVR System). According to the applicant, the SAPIEN M3 TMVR System is a transcatheter system designed to allow for replacement of the native mitral valve in patients with symptomatic mitral valve regurgitation or symptomatic mitral stenosis.

The following table provides an overview of the new technology add-on payment application for the SAPIEN M3 TMVR System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251003XXUEG>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Preliminary CMS Assessment                                                     |
|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | N/A                                                                            |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> Indications for use include (1) the treatment of symptomatic, moderate-to-severe or severe primary or secondary mitral regurgitation in patients deemed refractory to guideline directed medical therapy (for patients with secondary mitral regurgitation only) and unsuited for surgery or transcatheter edge-to-edge repair by a multidisciplinary heart team experienced in mitral valve therapies, and (2) the treatment of symptomatic severe mitral valve dysfunction (moderate-to-severe or severe mitral regurgitation, severe mitral stenosis, or moderate mitral regurgitation with moderate or greater mitral stenosis) associated with severe mitral annular calcification in patients who are deemed unsuited for mitral valve surgery.</p> <p><b>FDA Indication:</b> This device is indicated for the treatment of symptomatic moderate-to-severe or severe mitral regurgitation (MR) in patients who are deemed unsuitable for surgery or transcatheter edge-to-edge repair (TEER) therapy by a multidisciplinary heart team. It is also indicated for the treatment of symptomatic mitral valve dysfunction (moderate-to-severe or severe MR, severe mitral stenosis (MS), or moderate MR with moderate MS) associated with mitral annular calcification (MAC) in patients who are deemed unsuitable for surgery or TEER therapy by a multidisciplinary heart team.</p> | FDA indication is appropriate for consideration under the alternative pathway. |
| <b>Newness Period</b>                  | PMA approval on 12/22/2025                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Newness date: 12/22/2025.                                                      |
| <b>Cost Criterion</b>                  | <p>Scenario 1: 634 claims mapping to 11 MS-DRGs, with 43.85 percent of claims mapping to MS-DRG 266 (Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC).</p> <p>Scenario 2: 11,523 claims mapping to 2 MS-DRGs, with 54.16 percent of claims mapping to MS-DRG 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC).</p> <p>Final inflated average case-weighted standardized charge per case (Scenario 1— \$434,734; Scenario 2— \$344,193) exceeded the average case-weighted threshold amount (Scenario 1— \$234,166; Scenario 2— \$206,449).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Meets cost criterion.                                                          |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital is \$54,000 per patient. Per the applicant, while the system has multiple components (e.g., valve, docking station, etc.), they are all single-patient use and cannot be sold or used separately.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Maximum new technology add-on payment: \$35,100                                |

### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the SAPIEN M3 TMVR System meets the cost criterion and are therefore proposing to approve the SAPIEN M3 TMVR System for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table. We consider the beginning of the newness period to commence on December 22, 2025, the date on which the SAPIEN M3 TMVR System received FDA marketing authorization.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on

payment for a case involving the use of the SAPIEN M3 TMVR System would be \$35,100 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the SAPIEN M3 TMVR System meets the cost criterion and our proposal to approve new technology add-on payments for the SAPIEN M3 Transcatheter Mitral Valve Replacement System for FY 2027.

### 18. SetPoint System®

SetPoint Medical Corporation submitted a FY 2027 application for new technology add-on payments for

the SetPoint System®. According to the applicant, the SetPoint System® is a fully integrated, rechargeable, implantable vagus nerve stimulation system used to treat individuals with moderate to severe rheumatoid arthritis (RA) who have experienced a loss of efficacy, inadequate response, or intolerance to one or more biologic or targeted synthetic disease modifying antirheumatic drugs (DMARDs).

The following table provides an overview of the new technology add-on payment application for the SetPoint System® and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251006Y987F>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Preliminary CMS Assessment                                                     |
|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | N/A                                                                            |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> The SetPoint system is indicated for the treatment of adult patients with moderately to severely active RA who have had an inadequate response, loss of response or intolerance to one (1) or more biological or targeted synthetic DMARDs.</p> <p><b>FDA Indication:</b> This device is indicated for use in the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response, loss of response, or intolerance to one or more biological or targeted synthetic disease modifying antirheumatic drugs (b/tsDMARDs).</p> | FDA indication is appropriate for consideration under the alternative pathway. |
| <b>Newness Period</b>                  | <p>PMA approval on 7/30/2025</p> <p>Commercial availability delay to 8/21/2025 due to a delay in manufacturing.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Newness date: 8/21/2025.                                                       |
| <b>Cost Criterion</b>                  | <p>6,563 claims mapping to 2 MS-DRGs, with 76.84 percent of claims mapping to MS-DRG 041 (Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator).</p> <p>Final inflated average case-weighted standardized charge per case (\$292,843) exceeded the average case-weighted threshold amount (\$100.081).</p>                                                                                                                                                                                                                                                                                      | Meets cost criterion.                                                          |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital is \$59,500 per patient, for one complete SetPoint System®. The SetPoint System® includes an implantable Neuroimmune Modulator (\$56,500), a Silicone Pod (\$300), and a Charger and Docking Station (\$2,700) packaged into a single SKU/system package. The Charger and Docking Station is provided to the patient at the time of surgery and it is only usable by one patient.                                                                                                                                                                                                                   | Maximum new technology add-on payment: \$38,675                                |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the SetPoint System® meets the cost criterion and are therefore proposing to approve the SetPoint System® for new technology add-on payments for FY 2027, for the FDA approved indication covered by the Breakthrough Device designation listed in the table. We consider the beginning of the newness period to commence on August 21, 2025, the date on which the SetPoint System® became commercially available.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of

the SetPoint System® would be \$38,675 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the SetPoint System® meets the cost criterion and our proposal to approve new technology add-on payments for the SetPoint System® for FY 2027.

#### 19. Spur® Peripheral Retrievable Stent System

Reflow Medical, Inc. submitted a FY 2027 application for new technology add-on payments for the Spur® Peripheral Retrievable Stent System. According to the applicant, the Spur®

Peripheral Retrievable Stent System is used as an adjunct to percutaneous transluminal angioplasty (PTA) to dilate stenoses in infrapopliteal arteries ranging in diameter from 2.5 mm to 4.5 mm. We note that the applicant submitted an application for new technology add-on payments for this technology for FY 2026 (90 FR 18203 through 18205; 90 FR 36770).

The following table provides an overview of the new technology add-on payment application for the Spur® Peripheral Retrievable Stent System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251001G2LL6>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Preliminary CMS Assessment                        |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | X2HP38B, X2HQ38B, X2HR38B, X2HS38B, X2HT38B, and X2HU38B.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | No concerns.                                      |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> The Bare Temporary Spur Stent System is intended for the treatment of de novo or restenotic lesions of the infrapopliteal arteries to increase luminal gain.</p> <p><b>FDA Indication:</b> The Spur® Peripheral Retrievable Stent System is intended as an adjunct to percutaneous transluminal angioplasty (PTA) to dilate stenoses in infrapopliteal arteries ranging in diameter from 2.5 mm to 4.5 mm.</p> <p>Per the applicant, the Bare Temporary Spur Stent System named in the Breakthrough Device designation letter is the same device as the Spur® Peripheral Retrievable Stent System.</p> | FDA indication is appropriate for consideration.  |
| <b>Newness Period</b>                  | De Novo classification granted on 5/29/2025.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Newness date: 5/29/2025.                          |
| <b>Cost Criterion</b>                  | <p>Scenario 1: 2,665 claims mapping to 75 MS-DRGs, with 17 percent of claims mapping to MS-DRG 271 (Other Major Cardiovascular Procedures with CC).</p> <p>Scenario 2: 12,708 claims mapping to 133 MS-DRGs, with 30.93 percent of claims mapping to MS-DRG 253 (Other Vascular Procedures with CC) and MS-DRG 271 (Other Major Cardiovascular Procedures with CC).</p> <p>Final inflated average case-weighted standardized charge per case (Scenario 1 – \$261,797; Scenario 2 – \$238,193) exceeded the average case-weighted threshold amount (Scenario 1 – \$140,905; Scenario 2 – \$140,008).</p>                                                      | Meets cost criterion.                             |
| <b>Technology Cost</b>                 | The average total cost of the system to the hospital is \$3,995 per patient, based on one system used per inpatient stay. Internal sales data was used to calculate the price received. The system costs include \$3,994 for the Spur Stent, and \$1 for the Spur Stent System Delivery Catheter.                                                                                                                                                                                                                                                                                                                                                            | Maximum new technology add-on payment: \$2,596.75 |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the Spur® Peripheral Retrievable Stent System meets the cost criterion and are therefore proposing to approve the Spur® Peripheral Retrievable Stent System for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table. We consider the beginning of the newness period to commence on May 29, 2025, the date on which the Spur® Peripheral Retrievable Stent System received FDA marketing authorization.

Based on preliminary cost information from the applicant at the time of this proposed rule, we are proposing that the maximum new

technology add-on payment for a case involving the use of the Spur® Peripheral Retrievable Stent System would be \$2,596.75 for FY 2027 (that is, 65 percent of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the Spur® Peripheral Retrievable Stent System meets the cost criterion and our proposal to approve new technology add-on payments for the Spur® Peripheral Retrievable Stent System for FY 2027.

#### 20. Trilogy™ Transcatheter Aortic Valve Regurgitation System

JenaValve submitted a FY 2027 application for new technology add-on payments for the Trilogy™

Transcatheter Aortic Valve Regurgitation System. According to the applicant, the Trilogy™ Transcatheter Aortic Valve Regurgitation System for transcatheter aortic valve implantation is deployed so that the Transcatheter Heart Valve (THV) expands radially at the native annulus and clips onto the native aortic leaflets to anchor the THV. Per the applicant, the THV is designed to anchor in the diseased regurgitant aortic valve.

The following table provides an overview of the new technology add-on payment application for the Trilogy™ Transcatheter Aortic Valve Regurgitation System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP25100691E86>.



|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Preliminary CMS Assessment                       |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | N/A                                              |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> Indications for use include aortic valve replacement for the relief of aortic regurgitation (AR) and AR-dominant mixed aortic valve disease, in eligible patients with severe native aortic valve regurgitation who are judged by a heart team (including at least one cardiac surgeon) to be eligible for the device and to be at high risk for open surgical aortic valve replacement (defined as STS-PROM score <math>\geq 8\%</math>, or if <math>&lt; 8\%</math>, a documented heart team agreement determines that significant co-morbidities are not captured by the STS-PROM score).</p> <p><b>FDA Indication:</b> This device is indicated for the treatment of symptomatic, severe native tricuspid aortic valve regurgitation (not due to acute endocarditis, rheumatic heart disease, or acute aortic dissection) in patients who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for surgical aortic valve replacement (i.e., predicted risk of surgical mortality <math>\geq 8\%</math> at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).</p> | FDA indication is appropriate for consideration. |
| <b>Newness Period</b>                  | PMA approval on 3/17/2026.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Newness date: 3/17/2026.                         |
| <b>Cost Criterion</b>                  | <p>408 claims mapping to 9 MS-DRGs, with 41.67 percent of claims mapping to MS-DRG 266 (Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC).</p> <p>Final inflated average case-weighted standardized charge per case (\$362,565) exceeded the average case-weighted threshold amount (\$245,485).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Meets cost criterion.                            |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital is \$39,500 per patient. The technology is a single device application and system, designed for single patient use only.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Maximum new technology add-on payment: \$25,675  |

#### Cost Criterion

After review of the information provided by the applicant, we agree with the applicant that the Trilogy™ Transcatheter Aortic Valve Regurgitation System meets the cost criterion and are therefore proposing to approve the Trilogy™ Transcatheter Aortic Valve Regurgitation System for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table. We consider the beginning of the newness period to commence on March 17, 2026, the date on which the Trilogy™ Transcatheter Aortic Valve Regurgitation System received FDA marketing authorization.

Based on preliminary information from the applicant at the time of this

proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of the Trilogy™ Transcatheter Aortic Valve Regurgitation System would be \$25,675 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether the Trilogy™ Transcatheter Aortic Valve Regurgitation System meets the cost criterion and our proposal to approve new technology add-on payments for the Trilogy™ Transcatheter Aortic Valve Regurgitation System for FY 2027.

#### 21. ViaOne™ Epicardial Access System

CardioVia Ltd. submitted a FY 2027 application for new technology add-on payments for the ViaOne™ Epicardial Access System (ViaOne™). According to the applicant, ViaOne™ is a sterile, single use device, designed to allow safe pericardial access utilizing a proprietary mechanism of entry into the pericardial sac with a blunt tip and a concealed needle.

The following table provides an overview of the new technology add-on payment application for ViaOne™ and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251001MFBVW>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Preliminary CMS Assessment                                                     |
|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | N/A                                                                            |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> The ViaOne device is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate placement of devices into the pericardial space for the diagnosis and treatment of Ventricular Tachycardia.</p> <p><b>FDA Indication:</b> The ViaOne Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach to deliver diagnostic and therapeutic interventions for ventricular tachycardia.</p> <p>Per the applicant, the ViaOne™ device named in the Breakthrough Device designation letter is the same device as the ViaOne™ Epicardial Access System.</p> | FDA indication is appropriate for consideration under the alternative pathway. |
| <b>Newness Period</b>                  | 510(k) clearance on 3/20/2025.<br>Commercial availability delay expected until 4/27/2026.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | See following discussion.                                                      |
| <b>Cost Criterion</b>                  | <p>4,517 claims mapping to 90 MS-DRGs, with 30.68 percent of claims mapping to MS-DRG 274 (Percutaneous and Other Intracardiac Procedures with MCC).</p> <p>Final inflated average case-weighted standardized charge per case (\$303,361) exceeded the average case-weighted threshold amount (\$180,573).</p>                                                                                                                                                                                                                                                                                                                                                                                | Meets cost criterion.                                                          |
| <b>Technology Cost</b>                 | The total anticipated cost to the hospital for the ViaOne™ Device is \$2,000 per patient. It is expected that one device will be utilized per inpatient hospital stay.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Maximum new technology add-on payment: \$1,300                                 |

#### Newness Period

After review of the information provided by the applicant, we note that, regarding commercial availability, the applicant stated that the technology would not be available for sale until April 27, 2026. The applicant stated that the original manufacturing partner permanently ceased operations, requiring the applicant to engage a new qualified manufacturer and conduct full verification and validation testing. The applicant also stated that delays in completion of the required FDA establishment registration and device listing process, and current aviation and international shipping constraints related to regional security developments are expected to further delay initial U.S. availability. We are interested in confirmation regarding the first date of availability for sale of ViaOne™ on the U.S. market (irrespective of purchase volume or when the first sale occurred).

#### Cost Criterion

We agree with the applicant that ViaOne™ meets the cost criterion and are therefore proposing to approve ViaOne™ for new technology add-on payments for FY 2027, for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table.

Based on preliminary information from the applicant at the time of this proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of ViaOne™ would be \$1,300 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invite public comments on whether ViaOne™ meets the cost criterion and our proposal to approve new technology add-on payments for

the ViaOne™ Epicardial Access System for FY 2027.

#### 22. VUNO Med-DeepCARS®

VUNO Med Inc. submitted a FY 2027 application for new technology add-on payments for VUNO Med-DeepCARS® (DeepCARS®). According to the applicant, DeepCARS® is an artificial intelligence based technology that monitors and assesses the risk of impending cardiac arrest within a 24-hour period among inpatients in general hospital wards.

The following table provides an overview of the new technology add-on payment application for DeepCARS® and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at <https://mearis.cms.gov/public/publications/ntap/NTP251004DL00M>.

|                                        | Applicant Statements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Preliminary CMS Assessment                      |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Unique ICD-10-PCS Code(s)?</b>      | Request submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | N/A                                             |
| <b>Breakthrough Device Requirement</b> | <p><b>Breakthrough Device Designation Indication:</b> VUNO Med-DeepCARS® utilizes commonly and routinely recorded vital signs (blood pressure, heart rate, respiratory rate, and body temperature), along with the corresponding time of measurement and patient age, extracted from the electronic medical records of general ward patients to compute the DeepCARS™ Score. The DeepCARS™ Score is intended to diagnose an elevated risk of impending cardiac arrest within a 24-hour period.</p> <p>DeepCARS™ is indicated for use by healthcare providers whenever there is need for displaying and / or monitoring DeepCARS™ Scores and presenting associated configurable warning states as an adjunct to clinical decision support. It is not intended to replace vital signs monitoring.</p> <p>DeepCARS™ is intended for the care of patients in general hospital wards (medical and surgical). It is not intended for use in intensive care units, emergency departments, and neonatal intensive care units.</p> <p>DeepCARS™ is intended for use with adult patients (≥ 18 years old), only.</p> <p><b>FDA Indication:</b> Pending.</p> | Pending FDA marketing authorization.            |
| <b>Newness Period</b>                  | Applicant anticipates FDA decision by May 1, 2026, consistent with its Breakthrough Device designation.<br>No commercial availability delay expected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Pending FDA marketing authorization.            |
| <b>Cost Criterion</b>                  | <p>Scenario 1: 4,993,178 claims mapping to 764 MS-DRGs, with 7.73 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV &gt;96 Hours with MCC).</p> <p>Scenario 2: 4,048,668 claims mapping to 764 MS-DRGs, with 6.44 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV &gt;96 Hours with MCC).</p> <p>Scenario 3: 4,989,786 claims mapping to 764 MS-DRGs, with 7.73 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV &gt;96 Hours with MCC).</p> <p>Scenario 4: 4,982,849 claims mapping to 763 MS-DRGs, with 7.72 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV &gt;96 Hours with MCC).</p> <p>Final inflated average case-weighted standardized charge per case (Scenario 1 – \$89,347; Scenario 2 – \$84,677; Scenario 3 – \$89,274; Scenario 4 – \$89,069) exceeded the average case-weighted threshold amount (Scenario 1 – \$79,876; Scenario 2 – \$79,903; Scenario 3 – \$79,837; Scenario 4 – \$79,754).</p>                                                                                                   | Meets cost criterion.                           |
| <b>Technology Cost</b>                 | The estimated average cost to the hospital is \$364.09 per patient, based on an analysis using the FY 2024 MedPAR file data. The applicant calculated the total number of Medicare FFS visits in a year for IPPS providers, and assigned subscription costs based on bed size). It then calculated the average cost per case per provider by dividing the assigned subscription cost by the projected number of all-patient visits, and derived the overall cost per case by averaging provider-level costs across all hospitals. Per the applicant, hospitals are expected to acquire the DeepCARS® technology under a tiered subscription model, with annual fees varying according to hospital bed size: each hospital would be charged a base rate of \$200,000 per year, supplemented by an additional \$200 per bed, up to a maximum annual cost of \$400,000.                                                                                                                                                                                                                                                                              | Maximum new technology add-on payment: \$236.66 |

**BILLING CODE 4120-01-C****Cost Criterion**

After review of the information provided by the applicant, we agree with the applicant that DeepCARS® meets the cost criterion and are therefore proposing to approve

DeepCARS® for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

Based on preliminary information from the applicant at the time of this

proposed rule, we are proposing that the maximum new technology add-on payment for a case involving the use of DeepCARS® would be \$236.66 for FY 2027 (that is, 65% of the average cost of the technology). We note that the cost information for this technology may be updated in the final rule based on

revised or additional information CMS receives prior to the final rule.

We invite public comments on whether DeepCARS® meets the cost criterion and our proposal to approve new technology add-on payments for VUNO Med-DeepCARS® for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

#### 7. Proposed Alternative Pathway Repeal for New Technology Add-on Payment and Outpatient Prospective Payment System (OPPS) Device Pass-Through

As discussed previously, in the FY 2020 and FY 2021 IPPS/LTCH PPS final rules (84 FR 42292 through 42297; 85 FR 58737 through 58739), we finalized a policy to establish an alternative inpatient new technology add-on payment pathway for certain transformative new devices and certain antimicrobial products. Under this pathway, FDA-designated Breakthrough Devices and QIDPs, and drugs approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway (sometimes collectively referred to in this section as "alternative pathway designations") are considered to be not substantially similar to existing technology for purposes of the new technology add-on payment, and do not need to meet the requirement under § 412.87(b)(1) that the technology represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. We also finalized a policy in the CY 2020 OPPS/ASC final rule to establish an alternative transitional pass-through payment pathway for devices that are part of the FDA's Breakthrough Devices Program and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation (84 FR 61295 through 61296). Under this alternative pathway, FDA-designated Breakthrough Devices are not evaluated for substantial clinical improvement under § 419.66(c)(2) for the purposes of determining device pass-through payment status. We refer readers to the CY 2026 OPPS/ASC final rule (90 FR 53632 through 53636) for additional background on the OPPS Pass-Through Payment for Devices.

We note that the Breakthrough Devices Program is intended to help patients have more timely access to designated medical devices by expediting their development,

assessment, and review.<sup>82</sup> The Breakthrough Device designation criteria are defined in section 515B(b) of the FD&C Act (21 U.S.C. 360e-3(b)), which provides for a Program for devices that: "(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and (2)(A) that represent breakthrough technologies; (B) for which no approved or cleared alternatives exist; (C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or (D) the availability of which is in the best interest of patients."<sup>83</sup> Per FDA guidance, a sponsor should demonstrate a reasonable expectation that the device could provide for more effective treatment or diagnosis of the disease or condition identified in the proposed indications for use.<sup>84</sup> FDA defines a QIDP as "an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or (2) qualifying pathogens listed by the Secretary under" section 505E(f) of the FD&C Act.<sup>85</sup> FDA believed the LPAD pathway would facilitate development and approval of certain antibacterial and antifungal drugs to treat serious or life-threatening infections in limited populations of patients with unmet needs. FDA may approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, under the LPAD pathway, if: The drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs; The drug meets the standards for approval under section 505(c) and (d) of the FD&C Act or the standards for licensure under section 351 of the Public Health Service Act; and FDA receives a written request from the

sponsor to approve the drug as a LPAD pathway drug.<sup>86</sup>

As discussed in the FY 2020 IPPS/LTCH PPS rulemaking (84 FR 42292 through 42297) and in the CY 2020 OPPS/ASC rulemaking (84 FR 61295 through 61296), we stated that we believed that the benefits of addressing barriers to healthcare innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes supported establishing the alternative pathway for new technology add-on payments and OPPS device pass-through payments. We also stated that we believed it was prudent to gain experience under this new alternative pathway for certain transformative new devices before expanding it to other special designations to allow us to evaluate the benefits of this proposed alternative pathway to facilitate beneficiary access to transformative new medical devices as well as any other considerations that may come to light after application of this new pathway (84 FR 42296).

As we have gained experience, we have concerns with the limited evaluation process for alternative pathway applications for new technology add-on and OPPS device pass-through payments, and after further consideration, we believe it is in the best interest of Medicare patients to refine our approach, to ensure that all new technologies approved for new technology add-on payment have demonstrated that the technology is not substantially similar to existing technologies and represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Similarly, we believe it is in the best interest of Medicare patients that new technologies approved for OPPS device pass-through payment status have demonstrated a substantial clinical improvement, that is, they substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part, compared to the benefits of a device or devices in a previously established category or other available treatment. Therefore, we are proposing to repeal the alternative pathway for new technology add-on payment and OPPS device pass-through applications, and require all applicants for new technology add-on payments and OPPS

<sup>82</sup> Breakthrough Devices Program Guidance for Industry and Food and Drug Administration Staff (September 15, 2023) <https://www.fda.gov/media/162413/download>.

<sup>83</sup> *Ibid.*

<sup>84</sup> *Ibid.*

<sup>85</sup> Qualified Infectious Disease Product Designation Questions and Answers Guidance for Industry (May 2021) <https://www.fda.gov/media/148480/download>.

<sup>86</sup> Limited Population Pathway for Antibacterial and Antifungal Drugs—the LPAD Pathway (Content current as of: 03/24/2025) <https://www.fda.gov/drugs/development-resources/limited-population-pathway-antibacterial-and-antifungal-drugs-lpad-pathway>.

device pass-through payments to demonstrate that they meet the same eligibility requirements to receive add-on payments and/or pass-through payments. We believe this proposed requirement will better align spending and value and ultimately support providers in delivering the best, data-driven care possible. By requiring all technologies to demonstrate that they offer a substantial clinical improvement as part of our evaluation process, we believe we will be better able to make evidence-based decisions on which technologies should receive these additional payments. We believe that holding all applicants to the same standards and requiring all applicants to demonstrate that their technologies meet the same criteria maintains our focus on new and innovative technologies that improve beneficiary health outcomes while strengthening the evidence base supporting our approval decisions for new technology add-on payment and OPPS device pass-through payment, ensuring value for American taxpayers and Medicare beneficiaries.

Therefore, we are proposing that for all applications received for new technology add-on payments for FY 2028 and subsequent fiscal years, including applications for FDA-designated Breakthrough Devices and QIDPs, or drugs approved under FDA's LPAD pathway, we would evaluate whether the technology is new and not substantially similar to an existing technology, and the technology must demonstrate that it meets the requirements under § 412.87(b) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. That is, beginning with applications received for new technology add-on payments for FY 2028 and subsequent fiscal years, all applicants would need to meet all three of the criteria as specified at § 412.87(b) and described earlier in this section in order to receive the additional payment: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Technologies that are currently under review for FY 2027 new technology add-on payments under the alternative pathway will remain eligible for

consideration for add-on payment under the alternative pathway. Technologies that have previously been approved for add-on payments under the alternative pathway will remain eligible for add-on payment under the alternative pathway. Consistent with our proposal to remove the alternative pathway for certain antimicrobial products currently at § 412.87(d), we would also remove the conditional approval process for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products that does not receive FDA marketing authorization by July 1 prior to the fiscal year for which the applicant applied for new technology add-on payments, as currently reflected at § 412.87(f)(3). Accordingly, beginning with the FY 2028 new technology add-on payment applications, in order to be eligible for consideration for the new technology add on payment for the upcoming fiscal year, all applicants would need to receive FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered, as reflected at § 412.87(f)(2).

We are proposing to amend § 412.87 to reflect these proposals by revising paragraphs § 412.87(c) and (d) and removing subparagraph 412.87(f)(3). We are also proposing related revisions to the title of paragraph (f) and subparagraphs (1) and (2) of paragraph (f) to reflect this proposed policy. We are also proposing to make a technical correction to the introductory text at § 412.87(d) to restore language that was previously removed in error, with additional revisions to reflect the proposed repeal. We are also proposing to make a technical correction to the introductory text at § 412.88(a)(2)(ii)(A) to reference § 412.88(a)(2)(ii)(C), consistent with our policy as finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69245 through 69252).

Similarly, we are proposing that all applications received for OPPS device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the CY 2028 OPPS application cycle ending on March 1, 2027, and applications received for subsequent calendar years would have to demonstrate that the technology met the requirements currently reflected at § 419.66(c)(2)(i). OPPS device pass-through payment applications submitted as of September 30, 2026, for devices that are part of the FDA's Breakthrough Devices Program and received FDA marketing authorization for the indication covered by the Breakthrough Device designation would

be evaluated and could be approved under the alternative pathway, provided that all other criteria have been met. Existing device category codes established based on the approval, either preliminary or via a final determination made in an OPPS/ASC final rule, including any device category codes established for approved alternative pathway applications received as of September 30, 2026, would continue to be eligible for device pass-through payment status and would remain in effect for at least 2 years, but no more than 3 years, consistent with § 419.66(g). Previously existing device category codes that were no longer eligible for device pass-through payment status would remain unchanged. We are proposing to revise paragraph § 419.66(c)(2)(ii) to reflect this proposed policy, effective October 1, 2026.

We believe these changes would be the most prudent and transparent method to allow us to improve our focus on facilitating payment for innovative, high-value technologies that improve care for Medicare beneficiaries. As we stated in the September 7, 2001 final rule (66 FR 46913), we believed the special payments for new technology should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. We also stated that where such an improvement was not demonstrated, we continued to believe the incentives of the DRG system would provide a useful balance to the introduction of new technologies. As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36672), even if a technology does not receive new technology add-on payments, CMS continues to pay for new technologies through the regular payment mechanism established by the DRG payment methodology. Similarly, as we stated in the CY 2026 OPPS/ASC final rule (90 FR 53635), if a technology does not obtain OPPS device pass-through payment status, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate Ambulatory Payment Classifications (APC) payment. Whether a technology receives new technology add-on payments or OPPS device pass-through payments does not affect coverage of the technology or the ability for Medicare providers to provide such technology to patients where appropriate.

In addition, we believe that holding all applicants to the same standards by

requiring all applicants to demonstrate that their technologies meet the same criteria would ensure that all applications undergo the same review process by CMS. For new technology add-on payment, this includes the opportunity to present at the New Technology Town Hall Meeting on the substantial clinical improvement criterion with regard to pending new technology add-on payment applications, and to have applications considered as part of the annual IPPS rulemaking. Furthermore, because the application and approval timelines for new technology add-on payments are the same for traditional and alternative application pathways, this proposal would not change the time to approval, except for technologies submitted under the alternative pathway for certain antimicrobial products, for which the conditional approval process would no longer be available. Likewise, for OPPI device pass-through, applications are submitted to CMS through the quarterly process, and all applications are subject to notice and comment rulemaking in the next applicable OPPI/ASC annual rulemaking cycle (80 FR 70417 through 70418). Applications, regardless of the pathway under which they apply, that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process may receive pass-through payment status prior to the final determination in the OPPI/ASC final rule. This proposal would not change the time to approval. Technologies that demonstrate they meet the criteria during the quarterly process may receive pass-through payment status prior to the final determination in the OPPI/ASC final rule. Technologies that demonstrate they meet the criteria during notice and comment rulemaking would receive pass-through payment status via a final determination in the OPPI/ASC final rule.

We would also be interested in information on alternate methods that stakeholders believe would more effectively or efficiently accomplish the goal of aligning payment with value by facilitating payment for innovative, high-value technologies that have demonstrated improved Medicare beneficiary health outcomes, such as alternative strategies for leveraging FDA designations.

We invite public comment on our proposal to require all applicants for new technology add-on payments and OPPI device pass-through payments to demonstrate that they meet the same requirements for eligibility.

### III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

#### A. Background

##### 1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We refer to this factor as the wage index. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2027 hospital wage index based on the statistical areas appears under section III.B of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. CMS collects these data on the Medicare cost report titled “Hospital and Hospital Health Care Complex Cost Report”, Form CMS–2552–10, Worksheet S–3, Parts II, III, and IV. The information collection is currently approved under OMB control number 0938–0050 and has a September 30, 2028, expiration date. Section 1886(d)(3)(E) of the Act also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2027 is discussed in section II.B of the Addendum to this proposed rule.

As discussed in section III.I of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2027 is

discussed in section II.A.4.b of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program to construct an occupational mix adjustment to the wage index. The information collection is currently approved under OMB control number is 0938–0907 and expires on December 31, 2028. A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2027 wage index appears under section III.E of the preamble of this proposed rule.

##### 2. Core-Based Statistical Areas (CBSAs) for the FY 2027 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. In accordance with section 1886(d)(3)(E) of the Act, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs) (FY 2005 IPPS final rule, 69 FR 49026 through 49032). In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Community Survey (ACS). In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. The current statistical areas (which were implemented beginning with FY 2025) are based on revised OMB delineations issued on July 21, 2023, in OMB Bulletin No. 23–01. According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (“the 2020 Standards”), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, ACS, and Census Population Estimates Program data) (we refer to these revised OMB delineations as the “new OMB delineations” in this proposed rule). A copy of OMB Bulletin No. 23–01 may be obtained at <https://bidenwhitehouse.archives.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf>. We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69253 through 69266) for a full discussion of our implementation of the new OMB delineations for the FY 2025 wage index. For FY 2027, we are proposing to continue to use the new OMB delineations that we adopted beginning with FY 2025 to calculate the area wage indexes and the transition periods, as we discuss below.

### 3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBA and constituent county has its own unique identifying code, a Federal Information Processing Standard (FIPS) county code. The FIPS county codes are maintained by the U.S. Census Bureau. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to use the FIPS county codes for purposes of crosswalking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates, which were effective October 1, 2017, beginning with the FY 2018 wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963). We refer the reader to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130) for a complete discussion of our adoption of FIPS county codes. For FY 2027, we are proposing to continue to use the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2027, Tables 2 and 3 associated with this proposed rule and the County to CBA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect the latest FIPS county code updates.

#### *B. Worksheet S–3 Wage Data for the Proposed FY 2027 Wage Index*

##### 1. Cost Reporting Periods Beginning in FY 2023 for FY 2027 Wage Index

The proposed FY 2027 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2023 (cost reports with a begin date on or after October 1, 2022 and before October 1, 2023). The FY 2026 wage indexes were based on data from cost reporting periods beginning during FY 2022.

The proposed FY 2027 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty).
- Home office costs and hours.
- Certain contract labor costs and hours including direct patient care (which includes nursing), certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient

care services (as discussed in the FY 2008 IPPS final rule with comment period (72 FR 47315 through 47317)).

- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590) and modified in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49505 through 49508)) and other deferred compensation costs.

Consistent with the wage index methodology for FY 2026, the proposed wage index for FY 2027 excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to Graduate Medical Education (GME) (teaching physicians and residents), certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2027 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally Qualified Health Centers (FQHCs), because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, as explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398), salaries, hours, and wage-related costs of Critical Access Hospitals (CAHs) are excluded from the wage index as we believe that removing CAHs from the wage index is prudent policy, given the substantial negative impact these hospitals have on the wage indexes in the areas where they are located and the minimal impact they have on the wage indexes of other areas. We refer the reader to the FY 2004 IPPS final rule (68 FR 45397 through 45398) for a complete discussion regarding the exclusion of CAHs from the wage index. Similar to our treatment of CAHs, as discussed later in this section, we exclude Rural Emergency Hospitals (REHs) from the wage index.

For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

##### 2. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to

suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to Inpatient Rehabilitation Facilities (IRFs), Inpatient Psychiatric Facilities (IPFs), Long-Term Care Hospitals (LTCHs), and for hospital outpatient services. We note, in the calendar year (CY) 2025 End-Stage Renal Disease (ESRD) PPS final rule (89 FR 89097–89116), CMS finalized a new ESRD PPS-specific wage index that is used to adjust ESRD PPS payments for geographic differences in area wages. We refer the reader to the CY 2025 ESRD PPS final rule for complete details regarding ESRD wage index. We further note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

##### 3. Verification of Worksheet S–3 Wage Data

The wage data for the proposed FY 2027 wage index were obtained from Worksheet S–3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 (OMB Control Number 0938–0050 with an expiration date September 30, 2028) for cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023. For wage index purposes, we refer to cost reports beginning on or after October 1, 2022, and before October 1, 2023, as the “FY 2023 cost report,” the “FY 2023 wage data,” or the “FY 2023 data.” Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the FY 2027 wage index includes FY 2023 data submitted to us as of January 21, 2026. For FY 2027, the wage data was not subject to a desk review by the Medicare Administrative Contractors (MACs). CMS performed a review of the wage data to identify and resolve aberrant data, such as analyzing the data from a regional and national level.

We note, in previous fiscal years, we reviewed and evaluated the audited wage data, and the impacts of the COVID–19 PHE on such data. For FY 2027, we have not identified any significant issues with the FY 2023 wage data itself in terms of our review of this data.

For the proposed FY 2027 wage index, we identified and excluded 68

providers with aberrant data that should not be included in the wage index. If data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2027 wage index. We also adjusted certain aberrant data and included these data in the wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to transmit any changes to the wage data no later than March 21, 2026.

In constructing the proposed FY 2027 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2023, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data

for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages.

As discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398) and FY 2025 IPPS/LTCH final rule (89 FR 69268), any hospital that is designated as a CAH or REH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index.

For the proposed FY 2027 wage index, we removed 7 hospitals that converted to CAH status and 2 hospitals that converted to REH status on or after January 24, 2025, the cut-off date for CAH and REH exclusion from the FY 2026 wage index, and through and including January 23, 2026, the cut-off date for CAH and REH exclusion from the FY 2027 wage index. We also note

that we removed 2 hospitals that converted to REH status prior to January 24, 2025. In summary, we calculated the proposed FY 2027 wage index using the Worksheet S-3, Parts II and III wage data of 3,006 hospitals.

For the proposed FY 2027 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the FY 2027 wage index associated with this proposed rule (available via the internet on the CMS website), includes separate wage data for the campuses of 26 multicampus hospitals. The following chart lists the multicampus hospitals by CMS certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

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| CCN of Main Campus of Multicampus Hospital | Full-Time Equivalent Percentage of Main Campus | CCN of Sub Campus of Multicampus Hospital | Full-Time Equivalent Percentage of Sub Campus | CCN of Second Sub Campus of Multicampus Hospital | Full-Time Equivalent Percentage of Second Sub Campus |
|--------------------------------------------|------------------------------------------------|-------------------------------------------|-----------------------------------------------|--------------------------------------------------|------------------------------------------------------|
| 050121                                     | 0.86                                           | 05B121                                    | 0.14                                          |                                                  |                                                      |
| 070010                                     | 0.85                                           | 07B010                                    | 0.15                                          |                                                  |                                                      |
| 070022                                     | 0.99                                           | 07B022                                    | 0.01                                          |                                                  |                                                      |
| 100029                                     | 0.54                                           | 10B029                                    | 0.46                                          |                                                  |                                                      |
| 140010                                     | 0.81                                           | 14B010                                    | 0.19                                          |                                                  |                                                      |
| 220074                                     | 0.9                                            | 22B074                                    | 0.1                                           |                                                  |                                                      |
| 310069                                     | 0.19                                           | 31B069                                    | 0.81                                          |                                                  |                                                      |
| 330103                                     | 0.71                                           | 33B103                                    | 0.29                                          |                                                  |                                                      |
| 330195                                     | 0.89                                           | 33B195                                    | 0.11                                          |                                                  |                                                      |
| 330214                                     | 0.77                                           | 33B214                                    | 0.23                                          |                                                  |                                                      |
| 330234                                     | 0.8                                            | 33B234                                    | 0.2                                           |                                                  |                                                      |
| 340040                                     | 0.93                                           | 34B040                                    | 0.07                                          |                                                  |                                                      |
| 340115                                     | 0.81                                           | 34B115                                    | 0.06                                          | 34C115                                           | 0.13                                                 |
| 360020                                     | 0.97                                           | 36B020                                    | 0.03                                          |                                                  |                                                      |
| 390115                                     | 0.82                                           | 39B115                                    | 0.18                                          |                                                  |                                                      |
| 390142                                     | 0.83                                           | 39B142                                    | 0.17                                          |                                                  |                                                      |
| 390307                                     | 0.91                                           | 39B307                                    | 0.09                                          |                                                  |                                                      |
| 420004                                     | 0.89                                           | 42B004                                    | 0.11                                          |                                                  |                                                      |
| 450033                                     | 0.96                                           | 45B033                                    | 0.04                                          |                                                  |                                                      |
| 450330                                     | 0.96                                           | 45B330                                    | 0.04                                          |                                                  |                                                      |
| 460051                                     | 0.78                                           | 46B051                                    | 0.22                                          |                                                  |                                                      |
| 510022                                     | 0.94                                           | 51B022                                    | 0.06                                          |                                                  |                                                      |
| 520009                                     | 0.74                                           | 52B009                                    | 0.26                                          |                                                  |                                                      |
| 520030                                     | 0.99                                           | 52B030                                    | 0.01                                          |                                                  |                                                      |
| 670062                                     | 0.87                                           | 67B062                                    | 0.13                                          |                                                  |                                                      |
| 670116                                     | 0.64                                           | 67B116                                    | 0.36                                          |                                                  |                                                      |

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We note that, in past years, in Table 2, we have placed a “B” to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the “B” to the third position of the CCN. Because all IPPS hospitals have a “0” in the third position of the CCN, we believe that placement of the “B” in this third position, instead of the “0” for the subordinate campus, is the most efficient method of identification and interferes the least with the other variable digits in the CCN. We also note that providers can have an additional second sub campus located in a different CBSA than the main campus and its other sub campus(es). Therefore, in order to uniquely identify a second sub campus, we place a “C” in the third position of the CCN.

**4. Process for Requests for Wage Index Data Corrections****a. Process for Hospitals To Request Wage Index Data Corrections**

The preliminary, unaudited Worksheet S-3 wage data files for the proposed FY 2027 wage index were made available on May 23, 2025, through the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2027-wage-index-home-page>.

On January 30, 2026, we posted a public use file (PUF) at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2027-wage-index-home-page> containing FY 2027 wage index data available as of January 30, 2026. This PUF contains a tab with the Worksheet S-3 wage data (which includes Worksheet S-3, Parts II

and III wage data from cost reporting periods beginning on or after October 1, 2022, through September 30, 2023; that is, FY 2023 wage data), a tab with the occupational mix data (which includes data from the CY 2022 occupational mix survey, Form CMS-10079), a tab containing the Worksheet S-3 wage data of hospitals deleted from the January 30, 2026 wage data PUF, and a tab containing the CY 2022 occupational mix data of the hospitals deleted from the January 30, 2026 occupational mix PUF. In a memorandum dated January 22, 2026, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 30, 2026, wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2027 Hospital Wage Index Development Timetable available at <https://www.cms.gov/files/document/fy-2027->

*hospital-wage-index-development-time-table.pdf*.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule.

In a memorandum dated April 16, 2025, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files and the CY 2022 occupational mix survey data files posted on May 23, 2025, and the process and timeframe for requesting revisions.

If a hospital wished to request a change to its data as shown in the May 23, 2025, preliminary wage data files and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 2, 2025. Hospitals were notified of these deadlines and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs.

November 14, 2025, was the date by which MACs were required to transmit revised wage index data files and occupational mix data files to CMS. CMS published the wage index PUFs that included hospitals' revised wage index data on January 30, 2026. Hospitals had until February 17, 2026, to submit requests to the MACs to correct errors in the January 30, 2026, PUF due to CMS or MAC mishandling of the wage index data, or to revise adjustments to their wage index data as included in the January 30, 2026, PUF. Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must have been received by the MAC by the February deadline (that is, by February 17, 2026, for the FY 2027 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 20, 2026. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) is April 3, 2026. Data that were incorrect in the preliminary or January 30, 2026, wage

index data PUFs, but for which no correction request was received by the February 17, 2026, deadline, are not considered for correction at this stage. In addition, April 3, 2026, is the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified after the January 30, 2026, PUF and at least 14 calendar days prior to April 3, 2026 (that is, by March 20, 2026), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 3, 2026, for the FY 2027 wage index). We refer readers to the FY 2027 Hospital Wage Index Development Timetable for complete details.

Hospitals were given the opportunity to examine Table 2 associated with this proposed rule, which is listed in section VI of the Addendum to this proposed rule and available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2027-wage-index-home-page>. Table 2 associated with the proposed rule contained each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the proposed FY 2027 wage index, which was constructed from FY 2023 data. We note that the proposed hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by late January 2026.

We plan to post the final wage index data PUFs on April 30, 2026, on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2027-wage-index-home-page>. The April 2026 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process (the process for disputing revisions submitted to CMS by the MACs by March 20, 2026, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier), as previously described.

After the release of the April 2026 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files.

Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 20, 2026.

- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 30, 2026, wage index PUFs.

- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2026 final wage index data PUFs, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC so that it is received no later than May 29, 2026. May 29, 2026, is also the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified on or after 13 calendar days prior to April 3, 2026 (that is, March 21, 2026), and at least 14 calendar days prior to May 29, 2026 (that is, May 15, 2026), that did not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital is notified on or after 13 calendar days prior to May 29, 2026 (that is, May 16, 2026), may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2027 Hospital Wage Index Development Timetable posted on the CMS website at <https://www.cms.gov/files/document/fy-2027-hospital-wage-index-development-time-table.pdf>, the May appeals are required to be submitted to CMS through an online submission process. We refer readers to the FY 2027 Hospital Wage Index Development Timetable for complete details.

Verified corrections to the wage index data received timely (that is, by May 29, 2026) by CMS and the MACs will be incorporated into the final FY 2027 wage index, which will be effective October 1, 2026.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2027 payment rates. Accordingly, hospitals

that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision is required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals will have access to the final wage index data PUFs by late April 2026, they have an opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2027 wage index by August 2026, and the implementation of the FY 2027 wage index on October 1, 2026. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 29, 2026, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with § 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) the MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error,

before the beginning of the fiscal year. For purposes of this provision, "before the beginning of the fiscal year" means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 29, 2026, for the FY 2027 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised § 412.64(k)(2) to specify that, effective October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) the MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 29, 2026, deadline for the FY 2027 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 29, 2026 deadline for the FY 2027 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; it can only be used for the current

Federal fiscal year. In situations where our policies will allow midyear corrections other than those specified in § 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

#### b. Process for Data Corrections by CMS After the January 30, 2026, Public Use File (PUF)

The process set forth with the wage index timetable discussed in section III.C.4 of the preamble of this proposed rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have a multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process. As noted above, for the development of the FY 2027 wage index, the wage data was not subject to a desk review by the MACs. As in past years, CMS conducted its own review of the data and, if necessary, hospitals

provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 30, 2026, PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, can facilitate additional editing of the data. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, for example, if a positive adjustment resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension costs was not incorporated in the data, CMS can correct the data error, and the hospital's average hourly wage will likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 30, 2026, PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this

process and the timeline for requesting review of such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency in instances where CMS makes data corrections after the January 30, 2026 PUF and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2027 Hospital Wage Index Development Timetable, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

### *C. Method for Computing the Proposed FY 2027 Unadjusted Wage Index*

The method used to compute the proposed FY 2027 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2021 IPPS/LTCH PPS final rule (see 85 FR 58758 through 58761), and we are not proposing any changes to this methodology. We have restated our methodology in this preamble section of this proposed rule.

*Step 1.*—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the wage index (in this case, for FY 2027, these were data from cost reports for cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023). In addition, we included data from hospitals that had cost reporting periods beginning prior to the October 1, 2022, begin date and extending into FY 2023 but that did not have any cost report with a begin date on or after October 1, 2022, and before October 1, 2023. We include this data because no other data from these hospitals will be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as data applicable to the fiscal year wage data being used to compute the wage index for those hospitals. We note that, if a hospital had more than one cost reporting period beginning during FY 2023 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was

more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

*Step 2.*—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a “revised” Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35. In calculating a hospital's Net Salaries (we note that we previously used the term “average” salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term “net” salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) – (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, 15.01 and 15.02, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A

employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4.

As noted above, the proposed FY 2027 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2023 (cost reports with a begin date on or after October 1, 2022 and before October 1, 2023). Per the instructions in Section 4005.2, Part II, Hospital Wage Index Information, of the Provider Reimbursement Manual, for cost reporting periods on or after October 1, 2015 and before October 1, 2022, hospitals reported salaries and hours for Home Office (and related organizations) Physician Part A—Administrative direct employees and employees under contract on Worksheet S3, Part II, Line 15.

Per the instructions in Section 4005.2, Part II, Hospital Wage Index Information, of the Provider Reimbursement Manual, for cost reporting periods on or after October 1, 2022, line 15 has been split into two lines with hospitals reporting salaries and hours for Home Office (and related organizations) Physician Part A—Administrative direct employees on Line 15.01 and salaries and hours for Home Office (and related organizations) Physicians Part A—Administrative under contract on Line 15.02. Since the FY 2027 wage index uses cost reports with a begin date in FY 2023, we propose including Lines 15.01 and 15.02 in the calculation of the FY 2027 wage index and future fiscal years.

In reviewing the wage data used for FY 2027, approximately 61 hospitals reported salaries and hours on Line 15 instead of Lines 15.01 and 15.02. Because this is the first year we are using Lines 15.01 and 15.02 and hospitals are still adjusting to this reporting change, for FY 2027, we are proposing to use Line 15 in the wage index calculation in addition to lines 15.01 and 15.02. We believe using Line 15 for the FY 2027 wage index will minimize disparities in the FY 2027 wage index by ensuring that the data informing the calculation are applied uniformly.

The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) – (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15 + Line 15.01 + Line 15.02) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52).

As noted above, for FY 2027 we are proposing to include Lines 15, 15.01 and Line 15.02 in this calculation. We are further proposing to use Lines 15.01 and 15.02 instead of Line 15 for future fiscal years.

*Step 3.—Hours.*—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. The formula for Total Hours (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) – (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15 + Line 15.01 + Line 15.02).

As noted above, for FY 2027 we are proposing to include Lines 15, 15.01 and Line 15.02 in this calculation. We are further proposing to use Lines 15.01 and 15.02 instead of Line 15 for future fiscal years.

*Step 4.*—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the “excluded rate”, which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula: (Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) – (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43).

We then compute the amounts of overhead salaries and hours to be allocated to the excluded areas by multiplying the previously discussed ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to the excluded areas using three steps:

- We determine the “overhead rate” (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to

exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following:

(Lines 26 through 43 – Lines 28, 33 and 35)/(((Line 1 + Lines 28, 33, 35) – (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) – (Lines 9 and 10)) + (Lines 26 through 43 – Lines 28, 33, and 35)).

- We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.

- We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

*Step 5.*—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2022, through April 15, 2024, for private industry hospital workers from data obtained from the Bureau of Labor Statistics’ (BLS’) Office of Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringe benefits) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing to make any changes to the usage of the ECI for FY 2027. The factors used to adjust the hospital’s data are based on the midpoint of the cost reporting period, as indicated in this proposed rule.

*Step 6.*—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications

under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

*Step 7.*—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

*Step 8.*—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

*Step 9.*—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

*Step 10.*—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSAs' wage index will be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and

42306). We believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the FY 2027 wage index, we note there is one urban CBSA for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website and contains the area wage indexes), we include a footnote to indicate to which CBSA this policy applies. This CBSA's wage index is calculated as described, based on the FY 2020 IPPS/LTCH PPS final rule methodology (84 FR 42305). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded.

We refer readers to section II of Appendix B of this proposed rule for the policy regarding rural areas that do not have IPPS hospitals.

*Step 11.*—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 listed in section VI of the Addendum to this proposed rule and available via the internet on the CMS website.

The following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306). For data that we consider to be “raw data,” such as the cost report data on Worksheets S–

3, Parts II and III, and the occupational mix survey data, we use such data “as is,” and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in “Step 5,” for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the ECI for compensation for each 30-day increment from October 14, 2022, through April 15, 2024, for private industry hospital workers from the BLS' Office of Compensation and Working Conditions data. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage of the ECI for FY 2027. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

**MIDPOINT OF COST REPORTING PERIOD**

| After      | Before     | Adjustment Factor |
|------------|------------|-------------------|
| 10/14/2022 | 11/15/2022 | 1.06254           |
| 11/14/2022 | 12/15/2022 | 1.05809           |
| 12/14/2022 | 01/15/2023 | 1.05376           |
| 01/14/2023 | 02/15/2023 | 1.04954           |
| 02/14/2023 | 03/15/2023 | 1.04543           |
| 03/14/2023 | 04/15/2023 | 1.04142           |
| 04/14/2023 | 05/15/2023 | 1.03752           |
| 05/14/2023 | 06/15/2023 | 1.03371           |
| 06/14/2023 | 07/15/2023 | 1.02991           |
| 07/14/2023 | 08/15/2023 | 1.02603           |
| 08/14/2023 | 09/15/2023 | 1.02206           |
| 09/14/2023 | 10/15/2023 | 1.01813           |
| 10/14/2023 | 11/15/2023 | 1.01436           |
| 11/14/2023 | 12/15/2023 | 1.01076           |
| 12/14/2023 | 01/15/2024 | 1.00721           |
| 01/14/2024 | 02/15/2024 | 1.00363           |
| 02/14/2024 | 03/15/2024 | 1.00000           |
| 03/14/2024 | 04/15/2024 | 0.99641           |

For example, the midpoint of a cost reporting period beginning January 1, 2023, and ending December 31, 2023, is June 30, 2023. An adjustment factor of 1.02991 was applied to the wages of a hospital with such a cost reporting period.

Previously, we would also provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto

Rico-specific standardized amount. Section 601 of Division O, Title VI (section 601) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by

section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2027, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the previously described methodology, the proposed FY 2027 unadjusted national average hourly wage is the following:

|                                                                 |                |
|-----------------------------------------------------------------|----------------|
| <b>Proposed FY 2027 Unadjusted National Average Hourly Wage</b> | <b>\$58.87</b> |
|-----------------------------------------------------------------|----------------|

#### D. Proposed Occupational Mix Adjustment to the FY 2027 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ

different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

#### 1. Use of 2022 Medicare Wage Index Occupational Mix Survey for the FY 2027 Wage Index

Section 304(c) of Appendix F, Title III of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS

to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program and to measure the earnings and paid hours of employment for such hospitals by occupational category. As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69275 through 69278), we collected data in 2022 to compute the occupational mix adjustment for the FY 2025, FY 2026, and FY 2027 wage indexes.

The FY 2027 occupational mix adjustment is based on a calendar year (CY) 2022 survey. Hospitals were required to submit their completed 2022

surveys (Form CMS–10079, OMB Control Number 0938–0907, expiration date December 31, 2028) to their MACs by July 1, 2023. The preliminary, unaudited CY 2022 survey data were posted on the CMS website on July 12, 2023.

## 2. Calculation of the Occupational Mix Adjustment for FY 2027

For FY 2027, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2027 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be “raw data,” such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data “as is,” and not round any of the individual line items or fields.

However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this proposed rule (which is available via the internet on the CMS website), which contains the proposed FY 2027 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C of the preamble of this proposed rule for a chart listing the

multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that will be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the proposed FY 2027 wage index. For the proposed FY 2027 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,006 hospitals, and we used the occupational mix surveys of 2,922 hospitals for which we also had Worksheet S–3 wage data, which represented a “response” rate of 97 percent (2,922/3,006). For the proposed FY 2027 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2027 occupational mix adjusted national average hourly wage is the following:

## Proposed FY 2027 Occupational Mix Adjusted National Average Hourly Wage

**\$58.82**

## 3. Deadline for Submitting the 2025 Medicare Wage Index Occupational Mix Survey for Use Beginning With the FY 2028 Wage Index

A new measurement of occupational mix is required for FY 2028. The FY 2028 occupational mix adjustment will be based on a new calendar year (CY) 2025 survey. The CY 2025 survey (Form CMS–10079, OMB Control Number 0938–0907, expiration date December 31, 2028) received OMB approval on December 30, 2025. The final CY 2025 Occupational Mix Survey Hospital Reporting Form is available on the CMS website at: [https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/2025-occupational-](https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/2025-occupational-mix-survey-hospital-reporting-form-cms-10079-wage-index-beginning-fy-2028)

*mix-survey-hospital-reporting-form-cms-10079-wage-index-beginning-fy-2028*. Hospitals are required to submit their completed 2025 surveys to their MACs by June 30, 2026. The preliminary, unaudited CY 2025 survey data will be posted on the CMS website in mid-July 2026. As with the Worksheet S–3, Parts II and III cost report wage data, CMS and the MACs may revise or verify data elements in hospitals’ occupational mix surveys as part of the FY 2028 wage index development process.

## 4. Proposed Occupational Mix Adjustment and the Proposed FY 2027 Occupational Mix Adjusted Wage Index

As discussed in section III.E of the preamble of this proposed rule, for FY

2027, we are applying the occupational mix adjustment to 100 percent of the FY 2027 wage index. We calculated the occupational mix adjustment using data from the 2022 occupational mix survey, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582–51586).

Based on the 2022 occupational mix survey data, the proposed FY 2027 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

| OCCUPATIONAL MIX NURSING SUBCATEGORY        | AVERAGE HOURLY WAGE |
|---------------------------------------------|---------------------|
| National RN                                 | \$60.49             |
| National LPN and Surgical Technician        | \$35.01             |
| National Nurse Aide, Orderly, and Attendant | \$23.58             |
| National Medical Assistant                  | \$23.11             |
| National Nurse Category                     | \$50.14             |



The proposed national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly

wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix

adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2022 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) the following:

|                                                                                 |     |
|---------------------------------------------------------------------------------|-----|
| National Percentage of Hospital Employees in the Nurse Category                 | 45% |
| National Percentage of Hospital Employees in the All Other Occupations Category | 55% |

#### *E. Hospital Redesignations and Reclassifications*

The following sections III.E.1 through III.E.4 discuss revisions to the wage index based on hospital redesignations and reclassifications. Specifically, hospitals may have their geographic area changed for wage index payment by applying for urban to rural reclassification under section 1886(d)(8)(E) of the Act (implemented at § 412.103), reclassification by the Medicare Geographic Classification Review Board (MGCRB) under section 1886(d)(10) of the Act, Lugar status redesignations under section 1886(d)(8)(B) of the Act, or a combination of the foregoing.

##### **1. Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Act, Implemented at § 412.103**

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at § 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act (such hospitals are referred to herein as “§ 412.103 hospitals”). The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2024 IPPS/LTCH final rule (88 FR 58971 through 58977) for a review of our policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49004) to calculate the rural floor with

the wage data of urban hospitals reclassifying to rural areas under § 412.103, and discussion of our modification to the calculation of the rural wage index and its implications for the rural floor.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41369 through 41374), we codified certain policies regarding multicampus hospitals in the regulations at §§ 412.92, 412.96, 412.103, and 412.108. We stated that reclassifications from urban to rural under § 412.103 apply to the entire hospital (that is, the main campus and its remote location(s)). We also stated that a main campus of a hospital cannot obtain Sole Community Hospital (SCH), Rural Referral Center (RRC), or Medicare Dependent Hospital (MDH) status, or rural reclassification under § 412.103, independently or separately from its remote location(s), and vice versa. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49012 and 49013), we added § 412.103(a)(8) to clarify that for a multicampus hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area, including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act. If a remote location of a hospital is located in a different CBSA than the main campus of the hospital, it is CMS’ longstanding policy to assign that remote location a wage index based on its own geographic area to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act). Hospitals are required to identify and allocate wages and hours based on FTEs for remote locations located in different CBSAs on Worksheet S–2, Part I, Lines 165 and 166 of form CMS–2552–10. In calculating wage index values, CMS identifies the allocated wage data for these remote locations in Table 2 with a “B” in the 3rd position of the CCN. These remote locations of hospitals with § 412.103 rural reclassification status in a different CBSA are identified in Table 2, and hospitals should evaluate

potential wage index outcomes for their remote location(s) when terminating MGCRB reclassification, or canceling § 412.103 rural reclassification status.

As discussed at § 412.103(f), the duration of an approved rural reclassification remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved. If a hospital located in an urban area was approved for a rural reclassification under § 412.103(a)(1), that reclassification will no longer be valid if the hospital is no longer located within a rural census tract of an MSA as determined by the Federal Office of Rural Health Policy (FORHP) of the Health Resources and Services Administration (HRSA). Therefore, we encourage all hospitals and CAHs with active rural reclassifications under section 1886(d)(8)(E) of the Act to review their original reclassification application and determine whether the reclassification status will still apply.

Finally, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69280), CMS finalized a policy regarding terminated or “tied-out” hospitals, to address our concerns regarding the impacts these hospitals would have on rural wage index values. Specifically, we finalized a policy that § 412.103 reclassifications would be considered cancelled for the purposes of calculating the area wage index for any hospital with a CCN listed as terminated or “tied-out” as of the date that the hospital ceased to operate with an active CCN. We stated that we will obtain and review the best available CCN termination status lists as of the § 412.103(b)(6) “lock-in” date (60 days after the proposed rule for the FY is displayed in the **Federal Register**), consistent with the wage index development timeline. The lock-in date is used to determine whether a hospital has been approved for § 412.103 reclassification in time for that status to be included in the upcoming year’s wage index development.

We noted that our policy to consider § 412.103 reclassifications cancelled for the purposes of calculating area wage

index for any hospital with a CCN listed as terminated or “tied-out” is not intended to alter or affect the qualification for Critical Access Hospital (CAH), Sole Community Hospital (SCH), or Rural Emergency Hospital (REH) statuses or to have other effects unrelated to hospital wage index calculations. The rural reclassification status will remain in effect for any period that the original PPS hospital remains in operation with an active CCN. For REH qualification requirement purposes, this will include the date of enactment of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which was December 27, 2020.

## 2. General Policies and Effects of MGCRB Reclassification and Treatment of Dual Reclassified Hospitals

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions not later than the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in §§ 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals’ reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596).

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under § 412.103. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under § 412.103 from the calculation of the rural floor, but we reverted to the pre-FY 2020 policy in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49002 through 49004). Hospitals that are geographically located in States without any rural areas are ineligible to apply for

rural reclassification in accordance with the provisions of § 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 urban to rural and MGCRB reclassifications. Prior to this amendment to the regulations, hospitals had to choose between a § 412.103 urban to rural reclassification which confers other rural benefits (Medicare provisions such as payments to disproportionate share hospitals (DSHs), and non-Medicare payment provisions, such as the 340B Drug Pricing Program administered by HRSA) besides the wage index under section 1886(d) of the Act or a reclassification under the MGCRB to solely increase its wage index. Under the amended regulations, a hospital that has an active MGCRB reclassification and is then approved for an urban to rural reclassification under § 412.103 will not lose its MGCRB reclassification. Additionally, a hospital is no longer required to cancel its § 412.103 reclassification in order to be approved for an MGCRB reclassification. By amending the regulations and allowing a hospital to pursue reclassification under the MGCRB while also maintaining a rural reclassification under § 412.103, hospitals are accorded the benefits of a § 412.103 urban to rural reclassification and the ability to use distance and average hourly wage criteria designated for rural hospitals to obtain a higher wage index value through an MGCRB reclassification. We note, for wage index calculation and payment purposes, when there is both a § 412.103 reclassification and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes.

Prior to FY 2024, we excluded hospitals with § 412.103 urban to rural redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved and is not terminated by the hospital within the established timelines, we considered the hospital’s geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016, IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930), in which we finalized the April 21, 2016, IFC, for a full

discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For FY 2024 and subsequent years, we refer readers to the FY 2024 IPPS/LTCH PPS final rule for discussion of our policy to include hospitals with a § 412.103 reclassification that also have an active MGCRB reclassification to another area in the calculation of the reclassified rural wage index (88 FR 58971 through 58977).

## 3. MGCRB Reclassification Issues for FY 2027

### a. FY 2027 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280. There are 707 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2027. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2027, hospitals reclassified beginning in FY 2025 or FY 2026 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 242 hospitals approved for wage index reclassifications in FY 2025 that will continue for FY 2027, and 263 hospitals approved for wage index reclassifications in FY 2026 that will continue for FY 2027. Of all the hospitals approved for reclassification for FY 2025, FY 2026, and FY 2027, 1,212 hospitals (approximately 37 percent of IPPS hospitals) are in a MGCRB reclassification status for FY 2027 (with 331 of these hospitals reclassified back to their urban geographic location). We note that several hospitals approved for MGCRB reclassifications may opt to terminate this status after the proposed rule, and in some cases prior year reclassification would become effective in its place. We refer readers to section III.F.3.b of the preamble of this proposed rule for information on the effects of implementation of the new OMB delineations on reclassified hospitals.

Under the regulations at § 412.273, hospitals that have applied to be reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a

decision on the application. Hospitals are also permitted to terminate an approved reclassification after the MGCRB issues a decision, provided the request for termination is received by the MGCRB within 45 days of the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register, or within 7 calendar days of receiving a decision of the Administrator's in accordance with § 412.273, whichever is later.

For information about the current process for withdrawing a 3-year MGCRB reclassification application, terminating an approved 3-year MGCRB reclassification, or canceling a previous termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as section III.E.3.b of the preamble of this proposed rule, the FY 2002 IPPS final rule (66 FR 39887 through 39888), and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations was included in the FY 2008 IPPS final rule (72 FR 47333), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150), and the FY 2026 IPPS/LTCH PPS final rule (90 FR 36847 through 36848).

Applications for FY 2028 reclassifications are due to the MGCRB by September 1, 2026. This is also the current deadline for canceling a previous wage index reclassification termination (reinstating a reclassification) under § 412.273(d) for the FY 2027 cycle.

Applications and other information about MGCRB reclassifications may be obtained beginning in mid-July 2026 via the internet on the CMS website at <https://www.cms.gov/medicare/regulations-guidance/geographic-classification-review-board>. This collection of information is approved under OMB Control Number 0938-0573 and expires on February 28, 2029.

**b. Proposed Revisions to § 412.230(c)(1) to Address Ferry Routes**

The regulation at 412.230(c)(1) requires that hospitals seeking reclassification to an area must submit appropriate data relating to its proximity to the area, including evidence of the shortest route over improved roads to the area and the distance of that route as proximity data. The MGCRB has denied reclassification requests using ferry routes, but these decisions were overturned via administrative appeal.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69281), commenters suggested revising the proximity data regulations to include waterways

traveled by ferry boats as equivalent to travel over improved roads. CMS agreed that a modification to § 412.230(c)(1) could reduce unnecessary appeals.

Therefore, we are proposing to modify 412.230(c)(1) to include ferry routes when mapping the shortest route. This change would minimize appeals of MGCRB decisions and reduce administrative burden for both CMS and hospitals. This proposal is consistent with our definition of mileage for purposes of proximity in the FY 2002 IPPS Final Rule (66 FR 39874–39875), where we stated that we believe that mileage should continue to be measured by the shortest route over improved roads maintained by any local, State, or Federal government entity for public use. Since most ferry routes are maintained by local, State, or Federal government entities for public transportation over water, similar to bridges, we consider it appropriate to treat them as improved roads.

We would apply the same measurement method for miles traveled on land to those traveled by ferry boat over water. That is, the MGCRB requires providers to submit map evidence from nationally recognized electronic mapping services (e.g., Google Maps, Bing Maps, MapQuest) showing the shortest route over improved roads from the front entrance of the hospital to the county line of the requested area and the distance of that route.<sup>87</sup> Miles traveled by ferry boat would also need to be mapped using a nationally recognized electronic mapping service and included as evidence of the shortest route.

We are proposing to revise the regulations at 412.230(c)(1) to state: “To demonstrate proximity to the area, the hospital must submit evidence from a nationally recognized electronic mapping service of the shortest route from the front entrance of the hospital over improved roads or waterways traveled by ferry boats to the county line of the requested area and the distance of that route.” We seek comment on this proposal.

**c. Proposed Clarification Regarding the Data Used for Reclassifying to an Area With a Lower Wage Index (412.230(a)(5)(i))**

MGCRB reclassifications are approved for a 3-year period, and when evaluating a hospital's request for reclassification, effective with reclassifications for FY 2003, section 1886(d)(10)(D)(vi)(II) of the Act requires that the MGCRB must

use the average of the most recent hospital wage survey data and the data from each of the two immediately preceding surveys. These data requirements are described in regulation at § 412.230(d)(2). CMS publishes this data in a “Three Year MGCRB Reclassification Data Applications” file during each application cycle on the CMS website.<sup>88</sup> We believe that using 3-year data improves wage index consistency, and reduces the likelihood that a single year of aberrant wage data in given area would impact the ability of hospitals to obtain geographic reclassification.

To be approved for an MGCRB reclassification, hospitals, in general, must demonstrate that their average hourly wage data is, on average, greater than their geographic area, and is similar to the area to which they seek to be reclassified. As described at § 412.230(a)(5)(i), hospitals also must demonstrate that the area to which they are reclassifying has a higher pre-reclassification wage index than the area they are geographically located. It has come to our attention that some view the data requirement of § 412.230(a)(5)(i) to be ambiguous and believe using only a single year of wage data is acceptable. It is CMS' longstanding position that, for all average hourly wage criteria described under § 412.230, the three-year weighted average data is required for approval by the MGCRB. To remove any ambiguity, we are therefore proposing to revise § 412.230(a)(5)(i) to explicitly state that the data submitted must comply with the requirements of § 412.230(d)(2). That is, for purposes of meeting the criterion at § 412.230(a)(5)(i), we are affirming that the most recent three-year average hourly wage data must be submitted for hospitals located in both the area the applicant is located, and hospitals in the area to which reclassification is sought. This clarification is consistent with prior decisions made by the MGCRB, and the required usage of published 3-year data has been upheld on appeal through the Administrator's review process. We seek comment on this proposal.

**d. Proposed Revisions to 412.230 To Waive Wage Data Comparisons for Hospitals Reclassifying to Home**

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45188–45190), urban hospitals with § 412.103 rural reclassifications are eligible to

<sup>87</sup> MGCRB Rules 5.2(A)(1), available at <https://www.cms.gov/medicare/regulations-guidance/geographic-classification-review-board/mgcrb-rules>.

<sup>88</sup> <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files>.

obtain MGCRB reclassifications to receive the wage index of another area. In that rulemaking, CMS also discussed the option of such a hospital reclassifying to its geographic labor market area, or its “home” area. When approved for a home area reclassification, the hospital may obtain the benefits of rural status, while receiving the wage index applied to other hospitals in its geographic urban area. These home area reclassifications have become significantly more common since FY 2022 rule, with nearly a quarter of all MGCRB approvals being to the hospital’s geographic home area in FY 2026. Under current regulations, obtaining a home area reclassification is a relatively simple process. There would be no proximity requirement, as the hospital is physically located in the labor market to which it is seeking reclassification. As discussed in the May 10, 2021 Interim final rule with comment period (86 FR 24736–24738) and in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45188–45190), CMS described several options to obtain MGCRB reclassification for hospitals with § 412.103 reclassification. For example, in meeting the criterion at § 412.230(a)(5)(i), restricting MGCRB reclassifications to labor market areas with lower pre-reclassified wages than the area the hospital is located, CMS allowed an urban hospital with a § 412.103 rural reclassification to be considered located either in its geographic area or in the rural area of the State. Regarding the criteria at § 412.230(d)(1)(iii)(C), confirming that the hospital’s wages are above average for its area (the 106/108 percent criterion), § 412.103 hospitals are permitted to compare their average hourly wage data to either the other hospitals in its geographic area, or to the hospitals in the state’s rural labor market area. Additionally, many § 412.103 hospitals also have obtained rural referral center status. The provision at § 412.230(d)(3)(i) waives the average hourly wage comparison requirement at § 412.230(d)(1)(iii)(C) for rural referral centers.

The only criterion that most home area reclassification applicants are required to meet is at § 412.230(d)(1)(iv). That is, if a hospital with a rural reclassification demonstrates that its 3-year average hourly wage is at least 82 percent of the average hourly wage of its own geographic labor market area (the area to which it is seeking a home area MGCRB reclassification), the MGCRB application would be approved. The 82 percent criterion was initially determined to cover more than two

standard deviations of wage variance within any given labor market area. Given these factors, it would be exceptionally rare for any hospital with a rural reclassification to be denied a home area MGCRB reclassification.

However, we are aware of a circumstance in which a home area MGCRB reclassification would be denied. The published wage data used for MGCRB reclassification is based on cost report data that could be up to three years old. Newly established hospitals (or remote locations of hospitals located in a different labor market area than the main campus of the hospital) would not yet have a cost report included in the current fiscal year wage index development process, and no average hourly wage data would be published. In this case, these hospitals and remote locations would not be eligible for individual MGCRB reclassification due to their inability to meet the § 412.230(d)(1)(iv) average hourly wage comparison.

Individual hospitals are required to have at least one year of published average hourly wage data in order to receive a wage index reclassification. Newly established hospitals or remote locations without published wage data that are included in a county group reclassification (§ 412.232 and § 412.234) with other hospitals are eligible for approval. However, individual reclassification requests would be denied. We believe this is the appropriate policy, as the MGCRB is required to review wage data to determine whether it is appropriate to grant an individual hospital the wage index of another labor market area. However, given the unique nature of a home area reclassification, it is difficult to see what policy objective would be achieved by denying a hospital a wage index based on its own geographic area. Therefore, we are proposing to waive the application of § 412.230(d)(1)(iv) for a hospital requesting reclassification to its geographic home area. Specifically, we are proposing to add an exception § 412.230(d)(6) to waive the application of requirements of § 412.230(d)(1)(iv) for hospitals with § 412.103 rural reclassification and are seeking MGCRB reclassification to their geographic labor market area. While CMS continues to have concerns with hospitals using § 412.103 in order to enhance the state’s rural floor, the scenario we are addressing would only affect situations where the inability to obtain a home area reclassification could lead to lower wage index value for the hospital. In such a case, a hospital would have the option to cancel its rural reclassification per the provision at § 412.103(g), and

receive the wage index of its geographic urban area. However, there are situations where canceling rural reclassification would have significant financial impacts on the hospital, particularly in scenarios where a hospital operates in multiple urban labor market areas. For example, if a hospital with a § 412.103 reclassification opens or acquires a remote location in a different urban labor market area, we apply a separate wage index to that remote location based on its location and reclassification status. That remote location would be ineligible for individual MGCRB reclassification until CMS reviewed a cost report that allocates wages between the inpatient locations. In this case, the new remote location would be assigned its state’s rural wage index based on the main campus’ rural status, not the urban wage index for its geographic area.

Given that the large majority of hospitals with § 412.103 rural reclassifications can obtain home area MGCRB reclassification, we see no compelling policy justification to restrict reclassification in such a narrow circumstance. The few hospitals potentially affected by this proposed policy would not have published wage data for at least first year of any MGCRB reclassification and, therefore, would have a negligible impact on the accuracy or consistency of overall wage index values. We believe this proposal to waive the application of § 412.230(d)(1)(iv) for hospitals requesting reclassification to its geographic home area would provide an equitable opportunity to obtain a competitive wage index for affected hospitals.

We seek comment on this proposal.

#### 4. Redesignations Under Section 1886(d)(8)(B) of the Act

##### a. Lugar Status Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the outmigration adjustment. In addition, in that rule, we adopted a minor procedural change that will allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the issuance of the proposed rule in the **Federal Register**) to waive its urban status for the full 3-

year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital will no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of the issuance of the proposed rule in the **Federal Register** for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to [wageindex@cms.hhs.gov](mailto:wageindex@cms.hhs.gov). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate Lugar status may be sent to [wageindex@cms.hhs.gov](mailto:wageindex@cms.hhs.gov). To ensure proper accounting, we request hospitals to include their CCN, and either “waive Lugar” or “reinstate Lugar”, in the subject line of these requests. When applicable, this election will result in a cancellation of a hospital’s rural reclassification status under § 412.103, effective October 1, 2026. We also inform hospitals that for the request to be approved, the hospital must terminate any active MGCRB reclassification. All requests, once approved, will remain in effect for the remainder of the 3-year out-migration adjustment period.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the outmigration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located will no longer qualify for an outmigration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital’s request to accept the

outmigration adjustment will be denied, and the hospital will be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values will be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it will be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act.

*F. Proposed Wage Index Adjustments: Rural Floor, Imputed Floor, State Frontier Floor, Out-Migration Adjustment, Cap on Wage Index Decrease Policies, and Continuation of Transition for the Discontinuation of the Low Wage Index Hospital Policy*

The following adjustments to the wage index are listed in the order that they are generally applied. First, the rural floor, imputed floor, and state frontier floor provide a minimum wage index. The rural floor at section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the wage index for hospitals in urban areas of a State may not be less than the wage index applicable to hospitals located in rural areas in that State. The imputed floor at section 1886(d)(3)(E)(iv) of the Act provides a wage index minimum for all-urban states. The state frontier floor at section 1886(d)(3)(E)(iii) of the Act generally requires that hospitals in frontier states cannot be assigned a wage index of less than 1.00. Next, the out-migration adjustment at section 1886(d)(13)(A) of the Act is applied, potentially increasing the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county or counties with a higher wage index. Finally, all hospital wage index decreases are capped at 5 percent of the hospital’s final wage index in the prior fiscal year, such that a hospital’s wage index would not be less than 95 percent of its final wage index for the prior fiscal year, according to the policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021).

1. Rural Floor

Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located

in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the rural floor. Section 3141 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the FY 2027 wage index associated with this proposed rule (which is available on the CMS website), and based on the calculation of the rural floor including the wage data of hospitals that have reclassified as rural under § 412.103, we estimate that 535 hospitals would receive the rural floor in FY 2027. The budget neutrality impact of the proposed application of the rural floor is discussed in section II.A.4.e of Addendum A of this proposed rule.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48784), CMS finalized a policy change to calculate the rural floor in the same manner as we did prior to the FY 2020 IPPS/LTCH PPS final rule, in which the rural wage index sets the rural floor. We stated that for FY 2023 and subsequent years, we would include the wage data of § 412.103 hospitals that have no Medicare Geographic Classification Review Board (MGCRB) or Lugar reclassification in the calculation of the rural floor, and include the wage data of such hospitals in the calculation of “the wage index for rural areas in the State in which the county is located” as referred to in section 1886(d)(8)(C)(iii) of the Act.

In the FY 2024 IPPS/LTCH final rule (88 FR 58971 through 58977), we finalized a policy change beginning that year to include the data of *all* § 412.103 hospitals, even those that have an MGCRB reclassification, in the calculation process for the rural floor and the calculation of “the wage index for rural areas in the State in which the county is located” as referred to in section 1886(d)(8)(C)(iii) of the Act. We explained that after revisiting the case law, prior public comments, and the relevant statutory language, we agreed that the best reading of section 1886(d)(8)(E)’s text that CMS “shall treat the [§ 412.103] hospital as being located in the rural area” is that it instructs CMS to treat § 412.103 hospitals the same as geographically rural hospitals for the wage index calculation.

Accordingly, in the FY 2024 IPPS/LTCH PPS final rule, we finalized a policy to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude “dual reclass” hospitals (hospitals with simultaneous § 412.103

and MGCRB reclassifications) that are implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. For additional information on these changes, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58971 through 58977).

## 2. Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the imputed floor policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that had stated that they were disadvantaged by the absence of rural hospitals to set a wage index floor for those States. We extended the imputed floor policy eight times since its initial implementation, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and expired on September 30, 2018. We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FYs 2014 through 2019 (78 FR 50589 through 50590, 79 FR 49969 through 49971, 80 FR 49497 through 49498, 81 FR 56921 through 56922, 82 FR 38138 through 38142, and 83 FR 41376 through 41380, respectively) and to the regulations at § 412.64(h)(4). For FYs 2019, 2020, and 2021, hospitals in all-urban states received a wage index that was calculated without applying an imputed floor, and we no longer included the imputed floor as a factor in the national budget neutrality adjustment.

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021, amended section 1886(d)(3)(E)(i) of the Act and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Unlike the imputed floor that was in effect from FYs 2005 through 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Section 1886(d)(3)(E)(iv)(IV) of the Act provides that, for purposes of the imputed floor wage index under clause (iv), the term all-urban State means a State in which there are no rural areas (as defined in section

1886(d)(2)(D) of the Act) or a State in which there are no hospitals classified as rural under section 1886 of the Act. Under this definition, given that it applies for purposes of the imputed floor wage index, we consider a hospital to be classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value.

Effective beginning October 1, 2021 (FY 2022), section 1886(d)(3)(E)(iv) of the Act reinstated the imputed floor wage index policy for all-urban States, with no expiration date, using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178) for further discussion of the original imputed floor calculation methodology implemented in FY 2005 and the alternative methodology implemented in FY 2013.

Based on data available for this proposed rule, States that would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States that would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2027, are identified in Table 3 (which is available on the CMS website) associated with this proposed rule. States with a value in the column titled “State Imputed Floor” are eligible for the imputed floor.

The regulations at § 412.64(e)(1) and (4) and (h)(4) and (5) implement the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2021. The imputed floor would continue to be applied for FY 2027 in accordance with the policies adopted in the FY 2022 IPPS/LTCH PPS final rule. For more information regarding our implementation of the imputed floor required by section 1886(d)(3)(E)(iv) of the Act, we refer readers to the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178).

## 3. State Frontier Floor for FY 2027

Section 10324 of Public Law 111–148 amended Section 1886(d)(3)(E) of the Act and added section 1886(d)(3)(E)(iii) of the Act to require that hospitals in frontier States cannot be assigned a wage index of less than 1.00. We refer readers to the regulations at § 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161). We are not proposing any changes to the frontier floor policy for FY 2027. In this proposed rule, 40 hospitals would receive the frontier floor value of 1.00

for their FY 2027 proposed wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. We note that while Nevada meets the criteria of a frontier State, all hospitals within the State currently receive a wage index value greater than 1.00.

The areas affected by the rural and frontier floor policies for the proposed FY 2027 wage index are identified in Table 3 associated with this proposed rule, which is available via the internet on the CMS website.

## 4. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the “out-migration” adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When section 1886(d)(13) was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the “long-form” survey, which the Census Bureau used at that time, and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was “short form” only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative data set based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that

were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in prior IPPS/LTCH PPS final rules, we have applied the same policies, procedures, and computations since FY 2012. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source. We also stated that we will consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate.

As discussed previously in section III.A.2, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69253 through 69266), CMS adopted revised Core-Based Statistical Area (CBSA) delineations from the OMB Bulletin 23–01, published July 21, 2023. The revised delineations incorporated population estimates based on the 2020 decennial census, as well as updated journey-to-work commuting data. The Census Bureau once again worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked, for use in developing a new out-migration adjustment based on new commuting patterns. We analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the ACS, utilizing 2016 through 2020 data. The Census Bureau produces county level commuting flow tables every 5 years using non-overlapping 5-year ACS estimates. The data includes demographic characteristics, home and work locations, and journey-to-work travel flows. The custom tabulation requested by CMS was specific to general medical and surgical hospital and specialty (except psychiatric and substance use disorder treatment) hospital employees (hospital sector Census code 8191/NAICS code 6221 and 6223) who worked in the 50 States, Washington, DC, and Puerto Rico and, therefore, provided information about commuting patterns of workers at the county level for residents of the 50 States, Washington, DC, and Puerto Rico.

For the ACS, the Census Bureau selects a random sample of addresses where workers reside to be included in the survey, and the sample is designed to ensure good geographic coverage. The ACS samples approximately 3.5 million

resident addresses per year.<sup>89</sup> The results of the ACS are used to formulate descriptive population estimates, and, as such, the sample on which the dataset is based represents the figures that would be obtained from a complete count.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69301), we finalized that for FY 2025 and subsequent years, the out-migration adjustment will be based on the data derived from the previously discussed custom tabulation of the ACS utilizing 2016 through 2020 (5-year) Microdata. We believe that these data are the most appropriate to establish qualifying counties, because they are the most accurate and up-to-date data that are available to us. For FY 2027, we are not proposing any changes to the methodology or data source for calculating the out-migration adjustment. Specifically, we are proposing that the FY 2027 out-migration adjustments continue to be based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment. We have applied these same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2027. We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602). Table 2 of this proposed rule (which is available on the CMS website) lists the proposed out-migration adjustments for the FY 2027 wage index. In addition, Table 4A associated with this proposed rule, “List of Counties Eligible for the Out Migration Adjustment under Section 1886(d)(13) of the Act” (also available on the CMS website), consists of the following: A list of counties that are eligible for the outmigration adjustment for FY 2027 identified by FIPS county code, the proposed FY 2027 out-migration adjustment, and the number of years the adjustment would be in effect. We refer readers to section V.I of the Addendum of this proposed rule for instructions on accessing IPPS tables that are posted on the CMS websites identified in this proposed rule.

<sup>89</sup> According to the Census Bureau, the effects of the public health emergency (PHE) on ACS activities in 2020 resulted in a lower number of addresses (~2.9 million) in the sample, as well as fewer interviews than a typical year.

## 5. Cap on Wage Index Decreases and Budget Neutrality Adjustment

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a wage index cap policy and associated budget neutrality adjustment for FY 2023 and subsequent fiscal years. Under this policy, we apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. A hospital's wage index will not be less than 95 percent of its final wage index for the prior FY. We note, as discussed below, that for FY 2027 we are proposing to continue the transitional payment exception that addresses the effects of the removal of the low wage index hospital policy. This proposed transitional payment exception would be applied after the application of the 5-percent cap.

Except for newly opened hospitals, we apply the cap for a fiscal year using the final wage index applicable to the hospital on the last day of the prior fiscal year. A newly opened hospital will be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it will not receive a cap for that first year, because it will not have been assigned a wage index in the prior year. The wage index cap policy is reflected at § 412.64(h)(7). We apply the cap in a budget neutral manner through a national adjustment to the standardized amount each fiscal year. For more information about the wage index cap policy and associated budget neutrality adjustment, we refer readers to the discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021).

For FY 2027, we would apply the wage index cap and associated budget neutrality adjustment in accordance with the policies adopted in the FY 2023 IPPS/LTCH PPS final rule. We refer readers to the Addendum of this proposed rule for further information regarding the budget neutrality calculations.

## 6. Continued Transition for the Discontinuation of the Low Wage Index Hospital Policy

In the FY 2025 interim final action with comment period (IFC) (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. For FY 2026 and subsequent fiscal years, consistent with the FY 2025 IFC, after considering the D.C. Circuit's



decision in *Bridgeport Hospital v. Becerra*, we discontinued the low wage index hospital policy and the application of the low wage index budget neutrality factor to the standardized amounts (90 FR 36854).

For FY 2025 and FY 2026, consistent with our past practice to establish temporary transition policies to mitigate short-term instability and payment fluctuations, we established transition policies for hospitals significantly impacted by the discontinuation of the low wage index hospital policy using our authority under section 1886(d)(5)(I) of the Act. The transitional payment exception for FY 2025 for those hospitals was equal to the additional FY 2025 amount a hospital would have been paid under the IPPS if its FY 2025 wage index were equal to 95 percent of its FY 2024 wage index. The transitional payment exception for FY 2026 was equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024 wage index.<sup>90</sup> For FY 2025, we opted not to budget neutralize the interim transition policy given the timing of the *Bridgeport Hospital v. Becerra* decision. However, for FY 2026, we finalized a payment transition with a budget neutrality adjustment through notice-and-comment rulemaking for hospitals facing significant reductions over two years that would not be sufficiently mitigated by the wage index cap policy at 42 CFR 412.64(h)(7). We refer readers to the FY 2025 IFC (89 FR 80405 through 80421) and to the FY 2026 IPPS/LTCH PPS Final Rule (90 FR 36855 through 36857) for a full discussion of these transitional payment policies.

Some hospitals that previously benefitted from the low wage index hospital policy would continue to experience decreases of approximately 5 percent or more per year from their FY 2024 wage index (with the low wage index hospital policy applied). For example, these hospitals may experience a decrease of 15 percent or more over the three years from their FY 2024 wage index to their proposed FY 2027 wage index (that is, approximately 5 percent or more per year over that time period). Therefore, we are proposing to extend the transitional exception to the calculation payments for FY 2027 for these hospitals in the same manner as we did for the FY 2026 wage index.

Similar to the FY 2026 transition, the transitional exception policy we are proposing for FY 2027 would continue to apply only to hospitals that benefitted from the FY 2024 low wage index hospital policy. For FY 2027, for example, we would compare the hospital's proposed FY 2027 wage index to the hospital's FY 2024 wage index if the hospital benefitted from the low wage index hospital policy in FY 2024. If the hospital is significantly impacted by the discontinuation of the low wage index hospital policy, meaning the hospital's proposed FY 2027 wage index is decreasing by more than 14.2625 percent<sup>91</sup> from the hospital's FY 2024 wage index, then the transitional payment exception for FY 2027 for that hospital would be equal to the additional FY 2027 amount the hospital would be paid under the IPPS if its FY 2027 wage index were equal to 85.7375 percent<sup>92</sup> of its FY 2024 wage index.<sup>93</sup> We note this proposed transitional payment exception would be applied after the application of the 5-percent cap described at 42 CFR 412.64(h)(7).

For example: assume the FY 2024 wage index for a hospital that benefitted from the low wage index hospital policy is 0.7600, and the hospital's proposed FY 2027 wage index is 0.6500. (If applicable, this proposed FY 2027 wage index value would include the 5-percent cap based on a comparison of the hospital's FY 2027 wage index prior to application of the 5-percent cap, to the hospital's FY 2026 wage index. We note that the FY 2026 wage index that will be used in this comparison is generally the FY 2026 wage index listed in Table 2 from the FY 2026 Final Rule in the column labeled "FY 2026 Wage Index With Cap". We note that all hospitals, regardless of whether the cap was applied to their FY 2026 wage

index, have a value in the column "FY 2026 Wage Index With Cap". Hospitals that did not have a cap applied to their FY 2026 wage index will display a wage index in this column without the cap.) The hospital's proposed FY 2027 wage index is decreasing by more than 14.2625 percent from the hospital's FY 2024 wage index [that is,  $0.6500 < 0.6516$  where  $0.6516 = (0.857375 \text{ times } 0.7600)$ ]. The proposed transitional payment exception for FY 2027 for this hospital is equal to the additional amount the hospital would be paid under the IPPS if its FY 2027 wage index were equal to 0.6516, which is 85.7375 percent of 0.7600, its FY 2024 wage index. We note that the hospital in this example would not qualify for the transitional payment exception in FY 2028 should the policy be extended if its 2028 wage index is more than 0.6190, which is 81.450625 percent (or  $0.95 - 4$ ) of its FY 2024 wage index of 0.7600.

Similar to the FY 2026 transition, we are proposing to make this policy budget neutral for FY 2027 through an adjustment applied to the standardized amount for all hospitals because: (1) the wage index cap policy at 42 CFR 412.64(h)(7) would have mitigated these FY 2027 wage index decreases had the combined payment effect of the FY 2025 and FY 2026 wage index and the transitional payment exception been reflected solely in the FY 2025 and FY 2026 wage index, and it would have done so in a budget neutral manner under our current regulations; and (2) the circumstances described in the FY 2025 IFC (89 FR 80405 through 80421) that caused us to decline to budget neutralize the interim FY 2025 transition policy are not applicable to subsequent years. In addition, implementing the proposed transition policy for FY 2027 in a budget neutral manner would be consistent with past practice. For example, we budget neutralized the FY 2015 wage index transition budget neutrality policy discussed earlier (79 FR 49956 through 49962). As we have discussed in other instances (89 FR 19398), we believed, and continue to believe, that transition policies should not increase estimated aggregate Medicare payments beyond the payments that would be made had we never proposed these transition policies. Therefore, we are proposing to use our authority under section 1886(d)(5)(I)(i) of the Act twice. First, we are proposing to adopt a narrow transitional exception to the calculation of FY 2027 IPPS for low wage index hospitals significantly impacted by the discontinuation of the low wage index

<sup>91</sup> Under the wage index cap policy at 42 CFR 412.64(h)(7), a hospital's wage index for a FY cannot be lower than  $0.95 \times$  its wage index from the prior FY. Over a 3-year period if its wage index were decreasing by more than 5 percent each year, this will mean a hospital's wage index for a FY cannot be lower than  $(0.95 \times 0.95 \times 0.95)$  times its wage index from three years earlier. Similarly for our proposed FY 2027 transitional exception policy, we are proposing that a hospital is significantly impacted by the discontinuation of the low wage index hospital policy if its FY 2027 wage index is less than  $(0.95 \times 0.95 \times 0.95)$  of its FY 2024 wage index, which equates to a decrease of more than 14.2625 percent.

<sup>92</sup>  $85.7375 \text{ percent} = 95 \text{ percent for FY 2025} \times 95 \text{ percent for FY 2026} \times 95 \text{ percent for FY 2027}$ . This can also be expressed as  $.95 - 3$ .

<sup>93</sup> We note that we are not proposing to change the FY 2027 wage index values under section 1886(d)(3)(E) for hospitals eligible for the proposed FY 2027 transitional exception policy on the basis of the exception; the proposed change will be applied as a separate step only for purposes of determining the hospitals' FY 2027 IPPS payments.

<sup>90</sup>  $90.25 \text{ percent} = 95 \text{ percent for FY 2025} \times 95 \text{ percent for FY 2026}$ . This can also be expressed as  $.95 - 2$ .



hospital policy. Second, we are proposing to exercise our authority again to do so in a budget neutral manner.<sup>94 95</sup> We refer the reader to section II.A.4.g of the Addendum of this proposed rule for complete details regarding the application of the transition for the discontinuation of the low wage index hospital policy budget neutrality factor.

We are also proposing to make a budget neutral equivalent exception under the capital IPPS. Under the capital IPPS, the adjustment for local cost variation is based on the hospital wage index value that is applicable to the hospital under the operating IPPS. We adjust the capital standard Federal rate so that the effects of the annual changes in the geographic adjustment factor (GAF) are budget neutral. As discussed in the FY 2025 IFC (89 FR 80408), since FY 2023, the GAFs reflect the wage index cap policy that limits any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline, to 95 percent of its prior year value. As described previously, some hospitals that previously benefitted from the low wage index hospital policy will experience decreases of 15 percent or more over the three years from their FY 2024 wage index (with the low wage index hospital policy applied) to their proposed FY 2027 wage index, at approximately 5 percent or more per year over that time period and for subsequent years. As such, similar to the FY 2025 and FY 2026 transition policies, we are proposing for FY 2027 to make a budget neutral equivalent exception under the capital IPPS.

#### *G. FY 2027 Wage Index Tables*

In this FY 2027 IPPS/LTCH PPS proposed rule, we have included the following wage index tables: Table 2 titled "Case-Mix Index and Wage Index Table by CCN"; Table 3 titled "Wage Index Table by CBSA"; Table 4A titled

"List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act"; and Table 4B titled "Counties redesignated under section 1886(d)(8)(B) of the Act (Lugar Counties)." We refer readers to section VI of the Addendum to this proposed rule for a discussion of the wage index tables for FY 2027.

#### *H. Proposed Labor-Related Share for the FY 2027 Wage Index*

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the diagnosis related group (DRG) prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share results in a higher payment.

In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36869 through 36873), we rebased and revised the hospital market basket to a 2023-based IPPS hospital market basket, which replaced the 2018-based IPPS hospital market basket, effective beginning October 1, 2025. Using the 2023-based IPPS market basket, we finalized a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2025. In addition, in FY 2026, we implemented this rebased labor-related share in a budget neutral manner (90 FR 36857

through 36858, 90 FR 37216 through 37217). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. In the FY 2026 IPPS/LTCH PPS final rule, we included in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the 2023-based IPPS market basket: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-Related Services as measured in the 2023-based IPPS market basket. For FY 2027, we are proposing to continue to use a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2026.

As discussed in section VI.B of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are

<sup>94</sup> We note that even more so than was the case for the FY 2025 and FY 2026 interim transition policy, the scope and magnitude of the FY 2027 transitional policy are much smaller than the low wage index hospital policy, and we expect this trend to continue as effects of discontinuing the low wage hospital policy diminish. As discussed in section VI of the preamble of this proposed rule, we estimate only 54 hospitals, out of the over 3,000 hospitals paid under the IPPS will receive FY 2027 transitional exception payments. Also, as discussed in section II. A 4 of the addendum to this proposed rule, as proposed, we applied a budget neutrality factor to the standardized amount.

<sup>95</sup> We note that because creating an exception to the calculation of the FY 2027 payments is in this circumstance functionally equivalent to adjusting the FY 2027 payments, the transitional exception can be alternatively considered a transitional adjustment.

subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2027, we are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI of the Addendum to this FY 2027 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflect the proposed national labor-related share. Table 1C, in section VI of the Addendum to this FY 2027 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflects the national labor-related share for hospitals located in Puerto Rico. For FY 2027, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2027, we are proposing to apply the wage index to a

labor-related share of 66.0 percent of the national standardized amount.

#### **IV. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2027 (§ 412.106)**

##### *A. General Discussion*

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals<sup>96</sup> that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. This method is commonly referred to as the “Pickle method.” The second method for qualifying for the DSH payment adjustment, which is the more

commonly used method, is based on the hospital’s disproportionate patient percentage (DPP), described below, under which the DSH payment adjustment is based on a complex statutory formula that includes the hospital’s geographic designation, the number of beds in the hospital, and the level of the hospital’s DPP.

A hospital’s DPP is the sum of two fractions: the “Medicare fraction” and the “Medicaid fraction.” The Medicare fraction (also known as the “SSI fraction” or “SSI ratio”) is computed by dividing the number of the hospital’s inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital’s total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital’s number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital’s total number of inpatient days in the same period.

| <b>DSH Eligibility</b> | <b>Qualifying Criteria</b>                                                                                                                                                                                                                                                                                                                                          |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Statutory Formula      | A hospital that has a disproportionate patient percentage equal to or exceeding 15 percent may qualify for the Medicare DSH adjustment. We refer readers to 42 CFR 412.106 for the specific eligibility criteria and payment formulas.                                                                                                                              |
| “Pickle Method”        | A hospital that is located in an urban area and has 100 or more beds may qualify to receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. |

Because the DSH payment adjustment is part of the IPPS, the statutory references to “days” in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10316 of the same Act and section 1104 of the Health Care and Education

Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. We refer to these provisions collectively as section 3133 of the Affordable Care Act. Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments on the basis of the hospital’s DPP under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise

would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital’s amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

Since FY 2014, section 1886(r) of the Act has required that hospitals that are eligible under section 1886(d)(5)(F) of the Act receive two separately calculated payments:

<sup>96</sup> See section 1886(d)(1)(B) of the Act for the definition of a “subsection (d) hospital”.

|                                         |                                                                                                                                             |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Medicare DSH Payment                    | An empirically justified DSH payment equal to 25% of the amount determined under the statutory formula in section 1886(d)(5)(F) of the Act. |
| Medicare DSH Uncompensated Care Payment | An uncompensated care payment determined as the product of 3 factors, as discussed in this section.                                         |

Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress.<sup>97</sup> We refer to this payment as the “empirically justified Medicare DSH payment.”

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospitals an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. In other words, the first

factor of the uncompensated care payment calculation is 75 percent of the payments that would otherwise be made as Medicare DSH payments under section 1886(d)(5)(F) of the Act.

Section 1886(r)(2)(B) of the Act provides that the second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified). As discussed in a later section, we note that the second factor is computed based on estimates of the total U.S. population.

Section 1886(r)(2)(C) of the Act provides that the third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the

Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital’s uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment amount determined by these factors as the “uncompensated care payment.” In brief, the uncompensated care payment for an individual hospital is the product of the following 3 factors:

|          |                                                                                                                                                            |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Factor 1 | 75% of the total amount of DSH payments that would otherwise be made under section 1886(d)(5)(F) of the Act.                                               |
| Factor 2 | 1 minus the percent change in the percent of individuals who are uninsured.                                                                                |
| Factor 3 | The hospital’s uncompensated care amount relative to the uncompensated care amount for all hospitals that receive DSH payments, expressed as a percentage. |

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which was established

through the exercise of the Secretary’s discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or of the periods selected to develop such estimates.

#### *B. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments*

The payment methodology under section 3133 of the Affordable Care Act applies to “subsection (d) hospitals” that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year to receive a Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the empirically justified Medicare DSH payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to “such subsection (d) hospitals” the

<sup>97</sup> <https://www.medpac.gov/document/march-2007-report-to-the-congress-medicare-payment-policy/>.

uncompensated care payment. Section 1886(r)(2)'s reference to "such subsection (d) hospitals" refers to hospitals that receive empirically justified Medicare DSH payments under section 1886(r)(1) for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we explained that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status (that is, eligibility to receive empirically justified Medicare DSH payments) for the applicable fiscal year (using the most recent data that is available). For this proposed rule, we estimated DSH status for all hospitals using the most recent available SSI ratios and information from the most recent available Provider Specific File. We note that FY 2023 SSI ratios available on the CMS website were the most recent available SSI ratios at the time of developing this proposed rule.<sup>98</sup> If more recent data on DSH eligibility becomes available before the final rule, we would use such data in the final rule. Our final determinations of a hospital's eligibility for empirically justified Medicare DSH and uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for FY 2027.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemakings for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. Eligible hospitals include the following:

- Subsection (d) Puerto Rico hospitals are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act (78 FR 50623 and 79 FR 50006).
- Sole community hospitals (SCHs) that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the fiscal year (based on the best available data at that time) subject to settlement through the cost report. If they receive interim empirically justified Medicare DSH payments in a fiscal year, they will also

be eligible to receive interim uncompensated care payments for that fiscal year on a per discharge basis. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).

- Medicare-dependent, small rural hospitals (MDHs) are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (FY 2012 IPPS/LTCH PPS final rule, 76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for interim empirically justified Medicare DSH and interim uncompensated care payments as we do for all other IPPS hospitals. Recently enacted legislation has extended the MDH program through December 31, 2026. We refer readers to section V.E. of the preamble of this proposed rule for further discussion of the MDH program. We will continue to make a determination concerning an MDH's eligibility for interim empirically justified Medicare DSH and uncompensated care payments based on the hospital's estimated DSH status for the applicable fiscal year.

- Transforming Episode Accountability Model (TEAM) is a new episode-based payment model (89 FR 68986). Hospitals participating in TEAM continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. The model started January 1, 2026.

- IPPS hospitals that participate in the proposed Comprehensive Care for Joint Replacement Expansion (CJR-X) Model would continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. We refer the reader to section X.C. of the FY2027 IPPS/LTCH proposed rule for further discussion on the CJR-X Model. CMS proposes beginning this model on October 1, 2027.

Ineligible hospitals include the following:

- Maryland hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Achieving Healthcare Efficiency through Accountable Design (AHEAD) Model, beginning January 1, 2026. Maryland hospitals are not paid under the IPPS and are ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act. Further information is available on the CMS website at <https://www.cms.gov/priorities/innovation/innovation-models/ahead>.

- SCHs that are paid under their hospital-specific rate are not eligible for Medicare DSH and uncompensated care payments (78 FR 50623 and 50624).

- Hospitals participating in the Rural Community Hospital Demonstration Program are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173).<sup>99</sup> The period of participation for the last hospital in the demonstration under the most recent legislative authorization (Pub. L. 116–260) will end on June 30, 2028. Under the payment methodology that applies during this most recent extension of the demonstration program, participating hospitals do not receive

<sup>99</sup> The Rural Community Hospital Demonstration Program was extended for a subsequent 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). The period of performance for this 5-year extension period ended on December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. The period of performance for this 5-year extension period ended December 31, 2021. The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) amended section 410A of Public Law 108–173 to extend the demonstration program for an additional 5-year period.

<sup>98</sup> <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh>.

empirically justified Medicare DSH payments, and they are excluded from receiving interim and final uncompensated care payments. At the time of development of this proposed rule, we believe 22 hospitals may participate in the demonstration program at the start of FY 2027. We note that if at the time of developing the final rule there is a different number of hospitals projected to participate in the demonstration program during FY 2027, we would use updated information in the FY 2027 final rule.

#### *C. Empirically Justified Medicare DSH Payments*

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the Secretary to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments.

Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising Medicare Administrative Contractors (MACs) to simply adjust subsection (d) hospitals' interim claim payments to an amount equal to 25 percent of what would have been paid if section 1886(r) of the Act did not apply. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments could be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html>.

#### *D. Supplemental Payment for Indian Health Service (IHS) and Tribal Hospitals and Puerto Rico Hospitals*

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051), we established a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico for FY 2023 and subsequent fiscal years. This payment was established to help to mitigate the impact of the decision to discontinue the use of low-income

insured days as a proxy for uncompensated care costs for these hospitals and to prevent undue long-term financial disruption for these providers. The regulations located at 42 CFR 412.106(h) govern the supplemental payment. In brief, the supplemental payment for a fiscal year is determined as the difference between the hospital's base year amount and its uncompensated care payment for the applicable fiscal year as determined under § 412.106(g)(1). The base year amount is the hospital's FY 2022 uncompensated care payment adjusted by one plus the percent change in the total uncompensated care amount between the applicable fiscal year (that is, FY 2027 for purposes of this rulemaking) and FY 2022, where the total uncompensated care amount for a fiscal year is determined as the product of Factor 1 and Factor 2 for that year. If the base year amount is equal to or lower than the hospital's uncompensated care payment for the current fiscal year, then the hospital would not receive a supplemental payment because the hospital would not be experiencing financial disruption in that year as a result of the use of uncompensated care data from the Worksheet S-10 in determining Factor 3 of the uncompensated care payment methodology.

For FY 2027, we are not proposing any changes to the methodology for determining the supplemental payments and we will calculate the supplemental payments to eligible IHS/Tribal and Puerto Rico hospitals consistent with the methodology described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051) and § 412.106(h).

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49048 and 49049), the eligibility and payment processes for the supplemental payment are consistent with the processes for determining eligibility to receive interim and final uncompensated care payments adopted in FY 2014 IPPS/LTCH PPS final rule. We note that the MAC will make a final determination with respect to a hospital's eligibility to receive the supplemental payment for a fiscal year, in conjunction with its final determination of the hospital's eligibility for DSH payments and uncompensated care payments for that fiscal year.

#### *E. Uncompensated Care Payments*

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three

factors, which are discussed in the next sections.

#### *1. Proposed Calculation of Factor 1 for FY 2027*

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. The regulations located at 42 CFR 412.106(g)(1)(i) govern the Factor 1 calculation. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amounts that would be paid for a fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, we would not know the precise aggregate empirically justified Medicare DSH payment amounts that would be paid for a fiscal year until cost report settlement for all IPPS hospitals is completed. Thus, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount. In brief, Factor 1 is the difference between the Secretary's estimates of: (1) the amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of section 1886(r) of the Act; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act.

In this FY 2027 IPPS/LTCH PPS proposed rule, consistent with the policy that has applied since the FY 2014 final rule (78 FR 50627 through 50631), we are determining Factor 1 from the most recently available estimates of the aggregate amount of Medicare DSH payments that would be made for FY 2027 in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments that would be made for FY 2027, both as calculated by CMS' Office of the Actuary (OACT). Consistent with the policy that has applied in previous years, these estimates will not be revised or updated subsequent to publication of our final projections in the FY 2027 IPPS/LTCH PPS final rule.

For this proposed rule, to calculate both estimates, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by OACT using the

most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent DPPs and Medicare DSH payment adjustments provided in the IPPS Impact File. The projection of Medicare DSH payments for the fiscal year is also partially based on OACT's Part A benefits projection model, which projects, among other things, inpatient hospital spending. Projections of DSH payments additionally require projections of expected increases in utilization and case-mix. The assumptions that were used in making these inpatient hospital spending, utilization, and case-mix projections and the resulting estimates of DSH payments for FY 2024 through FY 2027 are discussed later in this section and in the table titled "Factors Applied for FY 2024 through FY 2027 to Estimate Medicare DSH Expenditures Using FY 2023 Baseline."

For purposes of calculating Factor 1 and modeling the impact of this FY 2027 IPPS/LTCH PPS proposed rule, we used OACT's January 2026 Medicare DSH estimates, which were based on data from the December 2025 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2026 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2026 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are ineligible for empirically justified Medicare DSH payments and uncompensated care payments, they were excluded from the January 2026 Medicare DSH estimates. Because Maryland hospitals are not paid under the IPPS, they are also ineligible for empirically justified Medicare DSH payments and uncompensated care payments and were also excluded from OACT's January 2026 Medicare DSH estimates.

The 22 hospitals that CMS expects will participate in the Rural Community Hospital Demonstration Program in FY

2027 were also excluded from OACT's January 2026 Medicare DSH estimates because under the payment methodology that applies during the demonstration, these hospitals are not eligible to receive empirically justified Medicare DSH payments or uncompensated care payments.

For this proposed rule, using the data sources previously discussed, OACT's January 2026 estimates of Medicare DSH payments for FY 2027 without regard to the application of section 1886(r)(1) of the Act, is approximately \$15.303 billion. Therefore, also based on OACT's January 2026 Medicare DSH estimates, the estimate of empirically justified Medicare DSH payments for FY 2027, with the application of section 1886(r)(1) of the Act, is approximately \$3.826 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2027). Under § 412.106(g)(1)(i), Factor 1 is the difference between these two OACT estimates. Therefore, in this FY 2027 IPPS/LTCH PPS proposed rule, we are determining that Factor 1 for FY 2027 would be \$11.477 billion, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2027 (\$15.303 billion minus \$3.826 billion). We note that consistent with our approach in previous rulemakings, OACT intends to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2027 IPPS/LTCH PPS final rule.

We note that the Factor 1 estimates for IPPS/LTCH PPS proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and Factor 1 estimates for IPPS/LTCH PPS final rules are generally consistent with those used for the Midsession Review of the President's Budget. Consistent with historical practice, we expect the Midsession Review will have updated economic assumptions and actuarial

analysis, which will be used for the development of Factor 1 estimates in the FY 2027 IPPS/LTCH PPS final rule.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the "2025 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," available on the CMS website at <https://www.cms.gov/oact/tr/2025>. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

In this proposed rule, we include information regarding the data sources, methods, and assumptions employed by OACT's actuaries in determining our estimate of Factor 1. In summary, we indicate the historical HCRIS data update OACT used to estimate Medicare DSH payments. We also explain that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provide the components of all the update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. The discussion also includes descriptions of the "Other" and "Discharges" assumptions.

OACT's estimates for FY 2027 for this proposed rule began with a baseline of \$12.901 billion in Medicare DSH expenditures for FY 2023. The following table shows the factors applied to update this baseline through the current estimate for FY 2027:

| FACTORS APPLIED FOR FY 2024 THROUGH FY 2027 TO ESTIMATE MEDICARE DSH EXPENDITURES USING FY 2023 BASELINE |                                           |            |          |        |        |                                      |
|----------------------------------------------------------------------------------------------------------|-------------------------------------------|------------|----------|--------|--------|--------------------------------------|
| FY                                                                                                       | IPPS Hospital Market Basket Update Factor | Discharges | Case-Mix | Other  | Total  | Estimated DSH Payment (in billions)* |
| 2024                                                                                                     | 1.031                                     | 1.002      | 1.0000   | 1.0279 | 1.0620 | 13.701                               |
| 2025                                                                                                     | 1.029                                     | 1.022      | 1.0090   | 0.9937 | 1.0546 | 14.449                               |
| 2026                                                                                                     | 1.026                                     | 1.019      | 1.0075   | 0.9675 | 1.0188 | 14.721                               |
| 2027**                                                                                                   | 1.024                                     | 1.009      | 1.0050   | 1.0015 | 1.0395 | 15.303                               |

\*Rounded.

\*\* The FY 2027 figures reflect the proposed inpatient hospital market basket percentage increase and productivity adjustment and are based on the 4<sup>th</sup> quarter 2025 IHS Global Inc. (IGI) forecast, the most recent forecast available at the time of development of this proposed rule.

In this table, the discharges column shows the changes in the number of Medicare FFS inpatient hospital discharges. The discharge figures for FY 2024 and FY 2025 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. The discharge figures for FY 2026 and FY 2027 are assumptions based on recent historical experience and assumptions related to how many beneficiaries will be enrolled in MA plans.

The case-mix column shows the estimated change in case-mix for IPPS hospitals. The case-mix figures for FY 2024 and FY 2025 are based on actual claims data adjusted by a completion factor to account for incomplete claims data. The case-mix figure for FY 2026 is the expected transition to the case-mix for FY 2027. The FY 2027 case-mix is based on assumptions from the 2012 “Review of Assumptions and Methods of the Medicare Trustees’ Financial Projections” report by the 2010–2011 Medicare Technical Review Panel.<sup>100</sup>

The “Other” column reflects the change in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and IPPS discharges and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns.

The following table shows the factors that are included in the “IPPS Hospital Market Basket Update Factor” column of the previous table:

| FY   | IPPS Hospital Market Basket Percentage Increase | Productivity Adjustment | Documentation and Coding | Total Update Percentage |
|------|-------------------------------------------------|-------------------------|--------------------------|-------------------------|
| 2024 | 3.3                                             | 0.2                     | 0.0                      | 3.5                     |
| 2025 | 3.4                                             | 0.5                     | 0.0                      | 3.9                     |
| 2026 | 3.3                                             | 0.7                     | 0.0                      | 4.0                     |
| 2027 | 3.2                                             | 0.8                     | 0.0                      | 4.0                     |

Note: All figures in this table are the final inpatient hospital updates for the applicable fiscal year, except for the FY 2027 figures. The FY 2027 figures reflect the proposed inpatient hospital market basket percentage increase and productivity adjustment and are based on the 4<sup>th</sup> quarter 2025 IGI forecast, the most recent forecast available at the time of development of this proposed rule. We refer to section VI.B. of the preamble of this proposed rule for a complete discussion of the inpatient hospital market basket update for FY 2027.

We are inviting public comments on our proposed Factor 1 for FY 2027.

## 2. Calculation of Proposed Factor 2 for FY 2027

### a. Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified).

We are continuing to use the methodology that was used in fiscal years (FYs) 2018 through 2026 to determine Factor 2 for FY 2027—to use the National Health Expenditure Accounts (NHEA) data to determine the percentage point change in the percent of individuals who are uninsured. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198) for a complete discussion of the NHEA and why we determined, and continue

to believe, that it is the data source for the rate of uninsurance that best meets all our considerations and is consistent with the statutory requirement that the estimate of the rate of uninsurance be based on data from the Census Bureau or other sources the Secretary determines appropriate.

In brief, the NHEA represents the government’s official estimates of economic activity (*that is*, spending) within the health sector. The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct-purchase and employer-sponsored plans), Medicare, Medicaid, the Children’s Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. The NHEA data are publicly available on the CMS website at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html>.

To compute Factor 2 for FY 2027, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. For a complete discussion of the approach OACT used to prepare the NHEA’s estimate of the rate of uninsurance in 2013, including the data sources used, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58998–58999).

The next metrics needed to compute Factor 2 for FY 2027 are projections of the rate of uninsurance in calendar years (CYs) 2026 and 2027 for the total U.S. population. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. The most recent projections are for 2024 through 2033 and were published on June 25, 2025. Those projections used the latest NHEA historical data that were available at the time of their construction (*that is*, all NHEA historical data through 2023). The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously noted. For a complete discussion of how the NHEA data account for expected changes in enrollment across all the categories of insurance coverage previously noted, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58999).

### b. Proposed Factor 2 for FY 2027

Using these data sources and the previously described methodologies, at the time of developing this proposed rule, OACT has estimated that the uninsured rate for the historical baseline year of 2013 was 14.0 percent, and that the uninsured rates for CYs 2026 and 2027 are projected to be 9.0 and 9.1 percent, respectively. As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS certified these

<sup>100</sup> <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/>

[reportstrustfunds/downloads/technicalpanelreport2010-2011.pdf](https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/technicalpanelreport2010-2011.pdf).



estimates. We refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for this proposed rule for further details on the methodology and assumptions that were used in the projection of these rates of uninsurance.<sup>101</sup>

As with the CBO estimates on which we based Factor 2 for fiscal years before FY 2018, the NHEA estimates are for a calendar year. Under the approach originally adopted in the FY 2014 IPPS/LTCH PPS final rule (79 FR 50014), we use a weighted average approach to project the rate of uninsurance for each fiscal year. We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years the fiscal year spans. Accordingly, in this proposed rule, we are continuing to apply the weighted average approach used in past fiscal years to estimate this proposed rule's rate of uninsurance for FY 2027.

OACT certified the estimate of the rate of uninsurance for FY 2027 determined using this weighted average approach to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act.<sup>1</sup> We note that we may also consider the use of more recent data that may become available before publication of the final rule, for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2027.

The calculation of the proposed Factor 2 for FY 2027 is as follows:

- Percent of individuals without insurance for CY 2013: 14.0 percent.
- Percent of individuals without insurance for CY 2026: 9.0 percent.
- Percent of individuals without insurance for CY 2027: 9.1 percent.
- Percent of individuals without insurance for FY 2027:  $(0.25 \text{ times } 0.090) + (0.75 \text{ times } 0.091) = 9.1 \text{ percent.}$
- FY 2027's proposed Factor 2 is calculated as  $1 \text{ minus the percent change in the percent of individuals without insurance between CY 2013 and FY 2027.}$
- Proposed Factor 2 is as follows:  $1 - |[(0.14 - 0.091)/0.14]| = 1 - 0.3500 = 0.6500.$

We propose that Factor 2 for FY 2027 would be 65.00 percent.

The proposed FY 2027 uncompensated care amount is

equivalent to proposed Factor 1 multiplied by proposed Factor 2, which is \$7,460,212,500.

We invite public comments on our proposed Factor 2 for FY 2027.

### 3. Calculation of Proposed Factor 3 for FY 2027

#### a. General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. To implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary for us to determine: (1) the definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (the estimated uncompensated care amount for an individual hospital) and the denominator (the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare

DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. For a discussion of the methodology, we used to calculate Factor 3 for fiscal years (FYs) 2014 through 2022, we refer readers to the FY 2024 IPPS/LTCH final rule (88 FR 59001 and 59002).

#### b. Background on the Methodology Used To Calculate Factor 3 for FY 2024 and Subsequent Years

Section 1886(r)(2)(C) of the Act governs the selection of the data to be used in calculating Factor 3 and allows the Secretary the discretion to determine the time periods from which we derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for a subsection (d) hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50634 through 50647), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments for a fiscal year and for those hospitals that we do not estimate will qualify for Medicare DSH payments for that fiscal year but that may ultimately qualify for Medicare DSH payments for that fiscal year at the time of cost report settlement.

As described in the FY 2022 IPPS/LTCH PPS final rule, commenters expressed concerns that the use of only 1 year of data to determine Factor 3 would lead to significant variations in year-to-year uncompensated care payments. Some stakeholders recommended the use of 2 years of

<sup>101</sup> See <https://www.cms.gov/files/document/certification-rates-uninsured-2027-proposed-rule.pdf>.



historical data from Worksheet S–10 data of the Medicare cost report (86 FR 45237). In the FY 2022 IPPS/LTCH PPS final rule, we stated that we would consider using multiple years of data when the vast majority of providers had been audited for more than 1 fiscal year under the revised reporting instructions. Audited FY 2020 cost reports were available for the development of the FY 2024 IPPS/LTCH PPS proposed and final rules. Feedback from previous audits and lessons learned were incorporated into the audit process for the FY 2020 reports.

In consideration of the comments discussed in the FY 2022 IPPS/LTCH PPS final rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49036 through 49047), we finalized a policy of using a multi-year average of audited Worksheet S–10 data to determine Factor 3 for FY 2023 and subsequent fiscal years. We explained our belief that this approach would be generally consistent with our past practice of using the most recent single year of audited data from the Worksheet S–10, while also addressing commenters' concerns regarding year-to-year fluctuations in uncompensated care payments. Under this policy, we used a 2-year average of audited FYs 2018 and 2019 Worksheet S–10 data to calculate Factor 3 for FY 2023. We also indicated that we expected FY 2024 would be the first year that 3 years of audited data would be available at the time of rulemaking. For FY 2024 and subsequent fiscal years, we finalized a policy of using a 3-year average of the uncompensated care data from the 3 most recent fiscal years for which audited data are available to determine Factor 3. Consistent with the approach that we followed when multiple years of data were previously used in the Factor 3 methodology, if a hospital does not have data for all 3 years used in the Factor 3 calculation, we will determine Factor 3 based on an average of the hospital's available data. For IHS and Tribal hospitals and Puerto Rico hospitals, we use the same multi-year average of Worksheet S–10 data to determine Factor 3 for FY 2024 and subsequent fiscal years as is used to determine Factor 3 for all other DSH-eligible hospitals (in other words, hospitals eligible to receive empirically justified Medicare DSH payments for a fiscal year) to determine Factor 3.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49033 through 49047), we also modified our policy regarding cost reports that start in one fiscal year and span the entirety of the following fiscal year. Specifically, in the rare cases when we use a cost report that starts in

one fiscal year and spans the entirety of the subsequent fiscal year to determine uncompensated care costs for the subsequent fiscal year, we would not use the same cost report to determine the hospital's uncompensated care costs for the earlier fiscal year. We explained that using the same cost report to determine uncompensated care costs for both fiscal years would not be consistent with our intent to smooth year-to-year variation in uncompensated care costs. As an alternative, we finalized our proposal to use the hospital's most recent prior cost report, if that cost report spans the applicable period.<sup>102</sup>

#### (1) Scaling Factor

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69323), we continued the policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042) to address the effects of calculating Factor 3 using data from multiple fiscal years, in which we apply a scaling factor to the Factor 3 values calculated for all DSH-eligible hospitals so that total uncompensated care payments to hospitals that are projected to be DSH-eligible for a fiscal year will be consistent with the estimated amount available to make uncompensated care payments for that fiscal year. Pursuant to that policy, we divide 1 (the expected sum of all DSH-eligible hospitals' Factor 3 values) by the actual sum of all DSH-eligible hospitals' Factor 3 values and then multiply the quotient by the uncompensated care payment determined for each DSH-eligible hospital to obtain a scaled uncompensated care payment amount for each hospital. This process is designed to ensure that the sum of the scaled uncompensated care payments for all hospitals that are projected to be DSH-eligible is consistent with the estimate of the total amount available to make uncompensated care payments for the applicable fiscal year.

#### (2) New Hospital Policy

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69323), we continued our new hospital policy that was modified in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042) and initially adopted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42370 through 42371) to

<sup>102</sup> For example, in determining Factor 3 for FY 2023, we did not use the same cost report to determine a hospital's uncompensated care costs for both FY 2018 and FY 2019. Rather, we used the cost report that spanned the entirety of FY 2019 to determine uncompensated care costs for FY 2019 and used the hospital's most recent prior cost report to determine its uncompensated care costs for FY 2018, provided that cost report spanned some portion of FY 2018.

determine Factor 3 for new hospitals. Consistent with our policy of using multiple years of cost reports to determine Factor 3, we defined new hospitals as hospitals that do not have cost report data for the most recent year of data being used in the Factor 3 calculation. Under this definition, the cut-off date for the new hospital policy is the beginning of the fiscal year after the most recent year for which audits of the Worksheet S–10 data have been conducted. For FY 2027, the FY 2023 cost reports are the most recent year of cost reports for which audits of Worksheet S–10 data have been conducted. Thus, hospitals with CMS Certification Numbers (CCNs) established on or after October 1, 2023, would be subject to the new hospital policy for FY 2027.

Under our modified new hospital policy, if a new hospital has a preliminary projection of being DSH-eligible based on its most recent available disproportionate patient percentage, it may receive interim empirically justified DSH payments. However, new hospitals will not receive interim uncompensated care payments because we would have no uncompensated care data on which to determine what those interim payments should be. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement. In FY 2025, while we continued to determine the numerator of the Factor 3 calculation using the new hospital's uncompensated care costs reported on Worksheet S–10 of the hospital's cost report for the current fiscal year, we determined Factor 3 for new hospitals using a denominator based solely on uncompensated care costs from cost reports for the most recent fiscal year for which audits have been conducted. In addition, we applied a scaling factor to the Factor 3 calculation for a new hospital.<sup>103</sup>

#### (3) Newly Merged Hospital Policy

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 690323 through 690324), we continued our policy of treating hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021), for these newly merged

<sup>103</sup> In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042), we explained our belief that applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, to improve consistency and predictability across all hospitals.

hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021 and 50022), we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year will be recalculated similar to new hospitals.

Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 690323 through 690324), we stated that we would continue to treat newly merged hospitals in a similar manner to new hospitals, such that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, the data from the newly merged hospital's cost report will be annualized for purposes of the Factor 3 calculation. Consistent with the methodology used to determine Factor 3 for new hospitals described in section IV.E.3. of the preamble of this proposed rule, we continued our policy for determining Factor 3 for newly merged hospitals using a denominator that is the sum of the uncompensated care costs for all DSH-eligible hospitals, as reported on Worksheet S–10 of their cost reports for the most recent fiscal year for which audits have been conducted. In addition, we apply a scaling factor, as discussed in section IV.E.3. of the preamble of this proposed rule, to the Factor 3 calculation for a newly merged hospital. In the FY 2025 IPPS/LTCH PPS final rule, we explained that consistent with past policy, interim uncompensated care payments for the newly merged hospital would be based only on the data for the surviving hospital's CCN available at the time of the development of the final rule.

#### (4) CCR Trim Methodology

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69324), we continued the policy of trimming CCRs, which we adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49043), for FY 2025. Under this

policy, we apply the following steps to determine the applicable CCR separately for each fiscal year that is included as part of the multi-year average used to determine Factor 3:

*Step 1:* Remove Maryland hospitals. In addition, we will remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

*Step 2:* Calculate a CCR “ceiling” for the applicable fiscal year with the following data: for each IPPS hospital that was not removed in Step 1 (including hospitals that are not DSH-eligible), we use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report will be selected.) The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.

*Step 3:* Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for the applicable fiscal year for hospitals within each State (including hospitals that are not DSH-eligible), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15.

*Step 4:* Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for the applicable fiscal year greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR “ceiling”).

*Step 5:* For hospitals that did not report a CCR on Worksheet S–10, Line 1, we assign them the statewide average CCR for the applicable fiscal year as determined in step 3.

After completing these steps, we recalculate the hospital's uncompensated care costs (Line 30) for the applicable fiscal year using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

#### (5) Uncompensated Care Data Trim Methodology

After applying the CCR trim methodology, there are rare situations where a hospital has potentially aberrant uncompensated care data for a fiscal year that are unrelated to its CCR.

Therefore, under the trim methodology for potentially aberrant uncompensated care costs (UCC) that was included as part of the methodology for purposes of determining Factor 3 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), if the hospital's uncompensated care costs for any fiscal year that is included as a part of the multi-year average are an extremely high ratio (greater than 50 percent) of its total operating costs in the applicable fiscal year, we will determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs for the applicable fiscal year.<sup>104</sup>

However, we note that we have audited the Worksheet S–10 data that will be used in the Factor 3 calculation for a number of hospitals. Because the UCC data for these hospitals have been subject to audit, we believe that there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, as we explained in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), we determined it is unnecessary to apply the UCC trim methodology for a fiscal year for which a hospital's UCC data have been audited.

In rare cases, hospitals that are not currently projected to be DSH-eligible and that do not have audited Worksheet S–10 data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69324 through 69325), we stated that in addition to the UCC trim methodology, we will continue to apply an alternative trim specific to certain hospitals that do not have audited Worksheet S–10 data for one or more of the fiscal years that are used in the Factor 3 calculation. For FY 2023 and subsequent fiscal years, in the rare case that a hospital's insured patients' charity care costs for a fiscal year are greater than \$7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total uncompensated care costs (line 30) is greater than 60 percent, we will not calculate a Factor 3 for the hospital at the time of proposed or final rulemaking. This trim will only impact hospitals that are not currently

<sup>104</sup> For example, if a hospital's FY 2018 cost report is determined to include potentially aberrant data, data from its FY 2019 cost report would be used for the ratio calculation.

projected to be DSH-eligible; and therefore, are not part of the calculation of the denominator of Factor 3, which includes only uncompensated care costs for hospitals projected to be DSH-eligible. Consistent with the approach adopted in the FY 2022 IPPS/LTCH PPS final rule, if a hospital would be trimmed under both the UCC trim methodology and this alternative trim, we apply this trim in place of the existing UCC trim methodology. We continue to believe this alternative trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the UCC trim methodology, because the UCC trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs.

Similar to the approach initially adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45245 and 45246), in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69324), we also stated that we would continue to use a threshold of 3 standard deviations from the mean ratio of insured patients' charity care costs to total uncompensated care costs (line 23 column 2 divided by line 30) and a dollar threshold that is the median total uncompensated care cost reported on most recent audited cost reports for hospitals that are projected to be DSH-eligible. We stated that we continued to believe these thresholds are appropriate to address potentially aberrant data. We also continued to include Worksheet S-10 data from IHS/Tribal hospitals and Puerto Rico hospitals consistent with our policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051). In addition, we continued our policy adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49044) of applying the same threshold amounts originally calculated for the FY 2019 reports to identify potentially aberrant data for FY 2025 and subsequent fiscal years to facilitate transparency and predictability. If a hospital subject to this trim is determined to be DSH-eligible at cost report settlement, the MAC will calculate the hospital's Factor 3 using the same methodology used to calculate Factor 3 for new hospitals.

#### c. Methodology for Calculating Factor 3 for FY 2027

For FY 2027, consistent with § 412.106(g)(1)(iii)(C)(11), we are following the same methodology as applied in FY 2024 and described in the previous section of the preamble of this proposed rule, to determine Factor 3 using the most recent 3 years of audited

cost reports, from FYs 2021, 2022, and 2023. Consistent with our approach for FY 2025, for FY 2027, we are also applying the scaling factor, new hospital, newly merged hospital, CCR trim methodology, UCC trim, and alternative trim methodology policies discussed in the previous section of the preamble of this proposed rule. For purposes of this proposed rule, we are using reports from the December 2025 HCRIS extract to calculate Factor 3. We intend to use the March 2026 update of HCRIS to calculate the final Factor 3 for the FY 2027 IPPS/LTCH PPS final rule.

Thus, for FY 2027, we will use 3 years of audited Worksheet S-10 Part 1 data to calculate Factor 3 for all eligible hospitals, including IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013, following steps. We note that these steps use Worksheet S-10, Part I, rather than Worksheet S-10, Part II, to calculate Factor 3.

*Step 1:* Select the hospital's longest cost report for each of the most recent 3 years of FY audited cost reports (FYs 2021, 2022, and 2023). Alternatively, in the rare case when the hospital has no cost report for a particular year because the cost report for the previous fiscal year spanned the more recent fiscal year, the previous fiscal year cost report will be used in this step. In the rare case that using a previous fiscal year cost report results in a period without a report, we would use the prior year report, if that cost report spanned the applicable period.<sup>105</sup> In general, we note that, for purposes of the Factor 3 methodology, references to a fiscal year cost report are to the cost report that spans the relevant fiscal year.

*Step 2:* Annualize the UCC from Worksheet S-10, Part I, Line 30, if a cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

*Step 3:* Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

*Step 4:* Calculate Factor 3 for all DSH-eligible hospitals using annualized uncompensated care costs (Worksheet S-10, Part I, Line 30) based on cost report data from the most recent 3 years

<sup>105</sup> For example, if a hospital does not have a FY 2021 cost report because the hospital's FY 2020 cost report spanned the FY 2021 time period, we will use the FY 2020 cost report that spanned the FY 2021 time period for this step. Using the same example, where the hospital's FY 2020 report is used for the FY 2021 time period, we will use the hospital's FY 2019 report if it spans some of the FY 2020 time period. We will not use the same cost report for both the FY 2021 and the FY 2020 time periods.

of audited cost reports (from Step 1, 2 or 3). New hospitals and other hospitals that are treated as if they are new hospitals for purposes of Factor 3 are excluded from this calculation.

*Step 5:* Average the Factor 3 values from Step 4; that is, add the Factor 3 values, and divide that amount by the number of cost reporting periods with data to compute an average Factor 3 for the hospital. Multiply by a scaling factor, as discussed in the previous section of the preamble of this proposed rule.

As we explained previously in this section, for FY 2027, we are also applying the scaling factor, new hospital, newly merged hospital, CCR trim methodology, UCC trim, and alternative trim methodology policies discussed in the previous section of the preamble of this proposed rule. For a hospital that is subject to either of the trims for potentially aberrant data (the UCC trim and alternative trim methodology explained in the previous section of the preamble of this proposed rule) and is ultimately determined to be DSH-eligible at cost report settlement, its uncompensated care payment will be calculated only after the hospital's reporting of insured charity care costs on its FY 2027 Worksheet S-10 has been reviewed. Accordingly, the MAC will calculate a Factor 3 for the hospital only after reviewing the uncompensated care information reported on Worksheet S-10 of the hospital's FY 2027 cost report. Then we will calculate Factor 3 for the hospital using the same methodology used to determine Factor 3 for new hospitals. Specifically, the numerator will reflect the uncompensated care costs reported on the hospital's FY 2027 cost report, while the denominator will reflect the sum of the uncompensated care costs reported on Worksheet S-10 of the FY 2023 cost reports of all DSH-eligible hospitals. In addition, we will apply a scaling factor, as discussed previously, to the Factor 3 calculation for the hospital.

Under the CCR trim methodology, for purposes of this FY 2027 IPPS/LTCH proposed rule, the statewide average CCR was applied to 12 hospitals' FY 2021 reports, of which 6 hospitals had FY 2021 Worksheet S-10 data. The statewide average CCR was applied to 10 hospitals' FY 2022 reports, of which 4 hospitals had FY 2022 Worksheet S-10 data. The statewide average CCR was applied to 12 hospitals' FY 2023 reports, of which 7 hospitals had FY 2023 Worksheet S-10 data.

For purposes of the FY 2027 IPPS/LTCH PPS final rule, consistent with our Factor 3 methodology since the FY 2014 IPPS/LTCH PPS final rule (78 FR

50642), we intend to use data from the March 2026 HCRIS extract for this calculation, which would be the latest quarterly HCRIS extract that is publicly available at the time of the development of the FY 2027 IPPS/LTCH PPS final rule.

Regarding requests from providers to amend and/or reopen previously audited Worksheet S–10 data for the most recent 3 cost reporting years that are used in the methodology for calculating Factor 3, we note that MACs follow normal timelines and procedures. For purposes of the Factor 3 calculation for the FY 2027 IPPS/LTCH PPS final rule, any amended reports and/or reopened reports would need to have completed the amended report and/or reopened report submission processes by the end of March 2026. In other words, if the amended report and/or reopened report is not available for the March HCRIS extract, then that amended and/or reopened report data would not be part of the FY 2027 IPPS/LTCH PPS final rule's Factor 3 calculation. We note that the March HCRIS data extract will be available during the comment period for this proposed rule if providers wanted to verify that their amended and/or reopened data is reflected in the March HCRIS extract.

#### d. Per-Discharge Amount of Interim Uncompensated Care Payments for FY 2027

Since FY 2014, we have made interim uncompensated care payments during the fiscal year on a per-discharge basis. Typically, we use a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the hospital's uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount for the applicable fiscal year is divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine the uncompensated care payment per discharge for that fiscal year.

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69328 and 69329), we finalized a policy to use a 3-year average of the most recent years of available historical discharge data to calculate a per-discharge payment amount that would be used to make interim uncompensated care payments to each projected DSH-eligible hospital during FY 2027 and subsequent fiscal years, codified at 42 CFR 412.106(i)(1). We are applying this policy for FY 2027. Interim uncompensated care payments made to a hospital during the fiscal year are reconciled following the end of the

year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the fiscal year.

As we explained in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69329 through 69330), we also finalized a voluntary process in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), through which a hospital may submit a request to its MAC for a lower per-discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the fiscal year and/or once during the fiscal year. In conjunction with this request, the hospital must provide supporting documentation demonstrating that there would likely be a significant recoupment at cost report settlement if the per-discharge amount is not lowered (for example, recoupment of 10 percent or more of the hospital's total uncompensated care payment, or at least \$100,000). For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its per-discharge uncompensated care payment amount. As another example, a hospital might request that its per-discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

Under the policy we finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 through 58834), the hospital's MAC will evaluate these requests and the supporting documentation before the beginning of the fiscal year and/or with midyear requests when the historical average number of discharges is lower than the hospital's projected discharges for the current fiscal year. If, following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that will be made is to lower the per-discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. If the MAC determines it would be appropriate to reduce the interim Medicare uncompensated care payment per-discharge amount, that updated amount will be used for purposes of the outlier payment calculation for the remainder

of the fiscal year. We are continuing to apply this policy for FY 2027. We refer readers to the Addendum in the FY 2023 IPPS/LTCH final rule for a more detailed discussion of the steps for determining the operating and capital Federal payment rate and the outlier payment calculation (87 FR 49431 through 49432). No change would be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, any change to the per-discharge uncompensated care payment amount will not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

#### e. Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with this proposed rule, we will publish on the CMS website a table listing Factor 3 for hospitals that we estimate will receive empirically justified Medicare DSH payments in FY 2027 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving an uncompensated care payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. However, we note that a Factor 3 will not be published for new hospitals and hospitals that are subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible.

We will also publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. In the DSH uncompensated care supplemental data file, we list new hospitals and the 17 hospitals that would be subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible, with a N/A in the Factor 3 column.

Hospitals have 60 days from the date of public display of this FY 2027 IPPS/LTCH PPS proposed rule in the **Federal Register** to review the table and supplemental data file published on the CMS website in conjunction with this proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of Worksheet S–10 data during the

report submission process.<sup>106</sup> Comments raising issues or concerns that are specific to the information included in the table and supplemental data file should be submitted by email to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We will address comments related to mergers and/or reporting upload discrepancies submitted to the CMS DSH inbox as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of the FY 2027 IPPS/LTCH PPS final rule. All other comments submitted in response to our proposals for FY 2027 must be submitted in one of the three ways found in the **ADDRESSES** section of this proposed rule before the close of the comment period in order to be assured consideration. In addition, we note that the CMS DSH inbox is not intended for Worksheet S–10 audit process related emails, which should be directed to the MACs.

We invite public comments on all the previously described proposals for Factor 3 for FY 2027.

## V. Other Decisions and Changes to the IPPS for Operating Costs

### A. Proposed Changes to MS–DRGs Subject to Postacute Care Transfer Policy and MS–DRG Special Payments Policies (§ 412.4)

#### 1. Background

Existing regulations at 42 CFR 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally

provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to (Fixed-Loss Outlier threshold for Nontransfer Cases adjusted for geographic variations in costs/Geometric Mean Length of Stay for the MS–DRG) \* (Length of Stay for the Case plus 1 day).

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. The statute at subparagraph 1886(d)(5)(J) of the Act directs CMS to identify MS–DRGs based on a high volume of discharges to postacute care facilities and a disproportionate use of postacute care services. As discussed in the FY 2006 IPPS final rule (70 FR 47416), we determined that the 55th percentile is an appropriate level at which to establish these thresholds. In that same final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific MS–DRG.

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6))). For an MS–

DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

Prior to the enactment of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), under section 1886(d)(5)(J) of the Act, a discharge was deemed a “qualified discharge” if the individual was discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection (d) hospital.
- A skilled nursing facility.
- Related home health services provided by a home health agency provided within a timeframe established by the Secretary (beginning within 3 days after the date of discharge).

Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care provided by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41394), we made conforming amendments to § 412.4(c) of the regulation to include discharges to hospice care occurring on or after October 1, 2018, as qualified discharges. We specified that hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) are subject to the postacute care transfer policy in accordance with this statutory amendment.

#### 2. Proposed Changes for FY 2027

As discussed in the preamble of this proposed rule, based on our analysis of FY 2025 MedPAR claims data, CMS proposed to make changes to a number of MS–DRGs, effective for FY 2027. Specifically, we are proposing the following changes:

- Reassigning an ICD–10–PCS code describing the insertion of an endocardiac pacing electrode to MS–DRGs 228–229, deleting MS–DRGs 258, 259, 260, 261 and 262, and creating proposed new MS–DRGs 210 and 211 (Cardiac Pacemaker Revision or Device Replacement with MCC and without MCC, respectively).

<sup>106</sup> For example, if the report does not reflect audit results due to MAC mishandling, or the most recent report differs from a previously accepted, amended report due to MAC mishandling.

- Reassigning the ICD-10-PCS codes describing extensive spinal fusions, fusions performed with a custom-made anatomically designed interbody fusion device and fusion of the sacroiliac joints using an internal fixation device with tulip connector from MS-DRGs 402, 426–428, 447–448, 450–451, and 456–458 to proposed new MS-DRGs 523, 524, and 525 (Extensive or Complex Spinal Fusion Procedures Except Cervical with MCC, with CC, and without CC/MCC, respectively).
- Redesignating an ICD-10-PCS code describing introduction of an antibiotic-eluting bone void filler from non-O.R. to non-O.R. affecting the MS-DRG assignment for MS-DRGs 463, 474, 477, 480, 492, 616, and 628.
- Deleting MS-DRGs 485–487, and creating proposed new MS-DRG 400 (Knee Procedures with Principal Diagnosis of Infection).
- Deleting MS-DRGs 466–468, and creating proposed new MS-DRG 449 (Revision of Hip or Knee Replacement).
- Creating proposed new MS-DRG 403 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC or Insertion of Antibiotic-eluting Bone Void Filler) and proposed new MS-DRG 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC).
- Deleting MS-DRGs 736, 737, 738, 739, 740 and 741 and creating proposed new MS-DRGs 731, 732, and 733 for uterine and adnexa procedures for female reproductive system malignancies.
- Deleting MS-DRG 264 (Other Circulatory System O.R. Procedures) and creating proposed new MS-DRGs 361 and 362 (Other Circulatory System O.R. Procedures with and without MCC, respectively).
- Adding ICD-10-PCS procedure codes describing the introduction of pancreatic islet cells to a new “Islet Cell Transplant Procedures” logic list in Pre-MDC MS-DRGs 008, 010, and 019.

When proposing changes to MS-DRGs that involve adding, deleting, and reassigning procedure or diagnosis codes between proposed new and revised MS-DRGs, we continue to believe it is necessary to evaluate the affected MS-DRGs to determine

whether they should be subject to the postacute care transfer policy. Considering the proposed changes to the MS-DRGs for FY 2027, according to the regulations under § 412.4(d), we evaluated the proposed new MS-DRGs using the general postacute care transfer policy criteria and data from the FY 2025 MedPAR file. We continue to believe it is appropriate to assess new MS-DRGs and reassess revised MS-DRGs when proposing reassignment of procedure codes or diagnosis codes that would result in material changes to an MS-DRG. We evaluated any current MS-DRG if we estimate that more than 5 percent of the current cases would shift from the current assigned MS-DRGs to proposed new MS-DRGs, or to a current MS-DRG from a proposed revised or deleted MS-DRG.

For existing MS-DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device), MS-DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC), and MS-DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC) and MS-DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) we determined that more than 5 percent of the current cases would shift from the current assigned MS-DRGs to proposed new MS-DRGs 523, 524, and 525. For existing MS-DRGs 463, 464, and 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC with CC, and without CC/MCC, respectively) and MS-DRGs 474, 475, and 476 (Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC, with CC, and without CC/MCC, respectively) we determined that more than 5 percent of the current cases would shift from the current assigned MS-DRGs to proposed new MS-DRGs 403 and 404. For existing MS-DRGs 616, 617, and 618 (Amputation of Lower Limb for Endocrine, Nutritional and Metabolic

Disorders with MCC, with CC, and without CC/MCC, respectively) we determined that more than 5 percent of the current cases would shift from the current assigned MS-DRGs to MS-DRGs 622, 623, and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders with MCC, with CC, and without CC/MCC, respectively). We note that for all other proposed changes, the relative volume of cases shifting to or from current MS-DRGs does not exceed the 5 percent threshold.

If an MS-DRG qualified for the postacute care transfer policy, we also evaluated that MS-DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6).

We note that proposed new and revised MS-DRGs 210, 361, 362, 400, 403, 404, 426, 457, 463, 464, 474, 475, 523, 524, 616, and 617 would qualify to be included on the list of MS-DRGs that are subject to the postacute care transfer policy. As described in the regulations at § 42 CFR 412.4(d)(3)(ii)(D), MS-DRGs that share the same base MS-DRG will all qualify under the MS-DRG postacute care transfer payment policy if any one of the MS-DRGs that share that same base MS-DRG qualifies. We therefore are proposing to add new or revised MS-DRGs 210, 211, 361, 362, 400, 403, 404, 456, 457, 458, 523, 524, and 525 to the list of MS-DRGs that are subject to the postacute care transfer policy. We note that MS-DRGs 426, 427, 428, 463, 464, 465, 474, 475, 476, 616, 617, and 618 are currently subject to the postacute care transfer policy. As a result of our review, these MS-DRGs, as proposed to be revised, would continue to qualify to be included on the list of MS-DRGs that are subject to the postacute care transfer policy.

Using the December 2025 update of the FY 2025 MedPAR file, we have developed the following table which sets forth the most recent analysis of the postacute care transfer policy criteria completed for this proposed rule with respect to each of these proposed new or revised MS-DRGs. For the FY 2027 final rule, we intend to update this analysis using the most recent available data at that time.

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| LIST OF PROPOSED NEW OR REVISED MS-DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2027 |                                                                                                                                                               |             |                                                                    |                                          |                                                                                                   |                                               |                                       |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|--------------------------------------------------------------------|------------------------------------------|---------------------------------------------------------------------------------------------------|-----------------------------------------------|---------------------------------------|
| Proposed New or Revised MS-DRG                                                                                 | MS-DRG Title                                                                                                                                                  | Total Cases | Postacute Care Transfer Cases (55 <sup>th</sup> percentile: 1,070) | Short-Stay Postacute Care Transfer Cases | Percent of Short-Stay Postacute Care Transfers to all Cases (55 <sup>th</sup> percentile: 9.693%) | FY 2026 Postacute Care Transfer Policy Status | Postacute Care Transfer Policy Status |
| 210                                                                                                            | Cardiac Pacemaker Revision or Device Replacement with MCC                                                                                                     | 2,938       | 1,539                                                              | 373                                      | 12.70%                                                                                            | New                                           | Yes                                   |
| 211                                                                                                            | Cardiac Pacemaker Revision or Device Replacement without MCC                                                                                                  | 3,942       | 1,214                                                              | 124                                      | 3.15%*                                                                                            | New                                           | Yes**                                 |
| 361                                                                                                            | Other Circulatory System O.R. Procedures with MCC                                                                                                             | 5,650       | 3,560                                                              | 1,094                                    | 19.36%                                                                                            | New                                           | Yes                                   |
| 362                                                                                                            | Other Circulatory System O.R. Procedures without MCC                                                                                                          | 2,711       | 1,664                                                              | 339                                      | 12.50%                                                                                            | New                                           | Yes                                   |
| 400                                                                                                            | Knee Procedures with Principal Diagnosis of Infection                                                                                                         | 1,555       | 1,147                                                              | 298                                      | 19.16%                                                                                            | New                                           | Yes                                   |
| 403                                                                                                            | Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint with MCC or Insertion of Antibiotic-eluting Bone Void Filler                          | 3,878       | 3,310                                                              | 1,278                                    | 32.96%                                                                                            | New                                           | Yes                                   |
| 404                                                                                                            | Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint without MCC                                                                           | 9,984       | 7,934                                                              | 2,039                                    | 20.42%                                                                                            | New                                           | Yes                                   |
| 426                                                                                                            | Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device            | 2,231       | 1,757                                                              | 561                                      | 25.15%                                                                                            | Yes                                           | Yes                                   |
| 427                                                                                                            | Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC                                                                          | 12,259      | 7,252                                                              | 976                                      | 7.96%*                                                                                            | Yes                                           | Yes**                                 |
| 428                                                                                                            | Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC                                                                   | 8,047       | 3,523                                                              | 379                                      | 4.71%*                                                                                            | Yes                                           | Yes**                                 |
| 449                                                                                                            | Revision of Hip or Knee Replacement                                                                                                                           | 984         | 690*                                                               | 181                                      | 18.39%                                                                                            | New                                           | No                                    |
| 456                                                                                                            | Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection or Extensive Fusions with MCC with MCC                                          | 966         | 800*                                                               | 302                                      | 31.26%                                                                                            | No                                            | Yes**                                 |
| 457                                                                                                            | Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection or Extensive Fusions with MCC with CC                                           | 2,352       | 1,564                                                              | 374                                      | 15.90%                                                                                            | No                                            | Yes                                   |
| 458                                                                                                            | Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection or Extensive Fusions with MCC without CC/MCC                                    | 1,145       | 472*                                                               | 69                                       | 6.03%*                                                                                            | No                                            | Yes**                                 |
| 463                                                                                                            | Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler | 6,697       | 5,566                                                              | 1,996                                    | 29.80%                                                                                            | Yes                                           | Yes                                   |

|     |                                                                                                                                          |        |        |       |        |     |       |
|-----|------------------------------------------------------------------------------------------------------------------------------------------|--------|--------|-------|--------|-----|-------|
| 464 | Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with CC                                 | 20,136 | 14,391 | 4,189 | 20.80% | Yes | Yes   |
| 465 | Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders without CC/MCC                          | 15,114 | 7,290  | 0     | 0%     | Yes | Yes** |
| 474 | Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler       | 2,397  | 1,993  | 778   | 32.46% | Yes | Yes   |
| 475 | Amputation for Musculoskeletal System and Connective Tissue Disorders with CC                                                            | 2,688  | 2,077  | 531   | 19.75% | Yes | Yes   |
| 476 | Amputation for Musculoskeletal System and Connective Tissue Disorders without CC/MCC                                                     | 336    | 196*   | 31    | 9.23%* | Yes | Yes** |
| 523 | Extensive or Complex Spinal Fusion Procedures Except Cervical with MCC                                                                   | 1,721  | 1,523  | 724   | 42.07% | New | Yes   |
| 524 | Extensive or Complex Spinal Fusion Procedures Except Cervical with CC                                                                    | 4,173  | 3,121  | 819   | 19.63% | New | Yes   |
| 525 | Extensive or Complex Spinal Fusion Procedures Except Cervical without CC/MCC                                                             | 722    | 413*   | 75    | 10.39% | New | Yes** |
| 616 | Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler | 3,239  | 2,420  | 896   | 27.66% | Yes | Yes   |
| 617 | Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with CC                                                      | 9,210  | 5,676  | 1,553 | 16.86% | Yes | Yes   |
| 618 | Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders without CC/MCC                                               | 45     | 22*    | 3     | 6.67%* | Yes | Yes** |
| 731 | Uterine and Adnexa Procedures for Malignancy with MCC                                                                                    | 1,276  | 589*   | 113   | 8.86%* | New | No    |
| 732 | Uterine and Adnexa Procedures for Malignancy with CC                                                                                     | 3,551  | 847*   | 98    | 2.76%* | New | No    |
| 733 | Uterine and Adnexa Procedures for Malignancy without CC/MCC                                                                              | 1,212  | 103*   | 0     | 0%*    | New | No    |

\* Indicates a current postacute care transfer policy criterion that the MS-DRG did not meet.

\*\* As described in the policy at 42 CFR 412.4(d)(3)(ii)(X), MS-DRGs that share the same base MS-DRG will all qualify under the postacute care transfer policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

During our annual review of proposed new or revised MS-DRGs and analysis

of the December 2025 update of the FY 2026 MedPAR file, we reviewed the list

of proposed revised or new MS-DRGs that qualify to be included on the list of



MS-DRGs subject to the postacute care transfer policy for FY 2027 to determine if any of these MS-DRGs would also be subject to the special payment methodology policy for FY 2027.

Based on our analysis of the proposed changes to the MS-DRGs included in the proposed rule, we determined that proposed new or revised MS-DRGs 362, 400, 404, 426, 457, 463, 617 met the criteria for the MS-DRG special payment methodology. As described in

the regulations at § 412.4(f)(6)(iv), MS-DRGs that share the same base MS-DRG will all qualify under the MS-DRG special payment policy if any one of the MS-DRGs that share that same base MS-DRG qualifies. Therefore, we are proposing that proposed new and revised MS-DRGs 361, 362, 400, 403, 404, 456, 457, 458, 463, 464, 465, 616, 617, 618 would be subject to the MS-DRG special payment methodology, effective for FY 2027. We note that MS-

DRGs 426, 427, and 428 are currently subject to the special payment methodology. As a result of our review, these MS-DRGs, as proposed to be revised, would continue to qualify to be included on the list of MS-DRGs that are subject to the special payment methodology.

For the FY 2027 final rule, we intend to update this analysis using the most recent available data at that time.

| LIST OF PROPOSED NEW OR REVISED MS-DRGs SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2027 |                                                                                                                                                               |                               |                                     |                                                           |                                       |                                        |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------------------------------|-----------------------------------------------------------|---------------------------------------|----------------------------------------|
| Proposed New or Revised MS-DRG                                                                         | MS-DRG Title                                                                                                                                                  | Geometric Mean Length of Stay | Average Charges of 1-Day Discharges | 50 Percent of Average Charges for all Cases within MS-DRG | FY 2026 Special Payment Policy Status | Proposed Special Payment Policy Status |
| 210                                                                                                    | Cardiac Pacemaker Revision or Device Replacement with MCC                                                                                                     | 5.38                          | \$74,709                            | \$81,538                                                  | New                                   | No                                     |
| 211                                                                                                    | Cardiac Pacemaker Revision or Device Replacement without MCC                                                                                                  | 2.61                          | \$80,943                            | \$48,765                                                  | New                                   | No                                     |
| 361                                                                                                    | Other Circulatory System O.R. Procedures with MCC                                                                                                             | 7.57                          | \$66,309                            | \$89,164                                                  | New                                   | Yes*                                   |
| 362                                                                                                    | Other Circulatory System O.R. Procedures without MCC                                                                                                          | 4.86                          | \$54,399                            | \$54,047                                                  | New                                   | Yes                                    |
| 400                                                                                                    | Knee Procedures with Principal Diagnosis of Infection                                                                                                         | 5.76                          | \$62,583                            | \$48,878                                                  | New                                   | Yes                                    |
| 403                                                                                                    | Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint with MMC or Insertion of Antibiotic-eluting Bone Void Filler                          | 8.96                          | \$89,936                            | \$119,673                                                 | New                                   | Yes*                                   |
| 404                                                                                                    | Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint without MCC                                                                           | 4.6                           | \$144,996                           | \$78,426                                                  | New                                   | Yes                                    |
| 426                                                                                                    | Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device            | 6.69                          | \$327,689                           | \$220,867                                                 | Yes                                   | Yes                                    |
| 427                                                                                                    | Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC                                                                          | 3.7                           | \$260,263                           | \$157,702                                                 | Yes                                   | Yes*                                   |
| 428                                                                                                    | Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC                                                                   | 2.51                          | \$268,894                           | \$133,790                                                 | Yes                                   | Yes*                                   |
| 456                                                                                                    | Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection or Extensive Fusions with MCC                                                   | 9.88                          | \$170,007                           | \$190,998                                                 | No                                    | Yes*                                   |
| 457                                                                                                    | Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection or Extensive Fusions with CC                                                    | 4.49                          | \$220,785                           | \$129,547                                                 | No                                    | Yes                                    |
| 458                                                                                                    | Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection or Extensive Fusions without CC/MCC                                             | 2.11                          | \$210,061                           | \$94,239                                                  | No                                    | Yes*                                   |
| 463                                                                                                    | Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler | 7.83                          | \$130,065                           | \$117,964                                                 | No                                    | Yes                                    |
| 464                                                                                                    | Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with CC                                                      | 3.02                          | \$122,058                           | \$75,972                                                  | No                                    | Yes*                                   |
| 465                                                                                                    | Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders without CC/MCC                                               | 1.37                          | \$118,741                           | \$59,454                                                  | No                                    | Yes*                                   |
| 474                                                                                                    | Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler                            | 9.61                          | \$59,684                            | \$92,799                                                  | No                                    | No                                     |
| 475                                                                                                    | Amputation for Musculoskeletal System and Connective Tissue Disorders with CC                                                                                 | 5.95                          | \$48,151                            | \$52,121                                                  | No                                    | No                                     |
| 476                                                                                                    | Amputation for Musculoskeletal System and Connective Tissue Disorders without CC/MCC                                                                          | 2.59                          | \$38,585                            | \$28,996                                                  | No                                    | No                                     |
| 523                                                                                                    | Extensive or Complex Spinal Fusion Procedures Except Cervical with MCC                                                                                        | 9.16                          | \$178,774                           | \$322,155                                                 | New                                   | No                                     |
| 524                                                                                                    | Extensive or Complex Spinal Fusion Procedures Except Cervical with CC                                                                                         | 5.54                          | \$221,131                           | \$231,868                                                 | New                                   | No                                     |
| 525                                                                                                    | Extensive or Complex Spinal Fusion Procedures Except Cervical without C or MCC                                                                                | 3.24                          | \$354,701                           | \$164,301                                                 | New                                   | No                                     |
| 616                                                                                                    | Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler                      | 8.3                           | \$46,909                            | \$72,353                                                  | No                                    | Yes*                                   |
| 617                                                                                                    | Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with CC                                                                           | 5.3                           | \$49,257                            | \$41,595                                                  | No                                    | Yes                                    |
| 618                                                                                                    | Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders without CC/MCC                                                                    | 3.37                          | \$8,517                             | \$28,277                                                  | No                                    | Yes*                                   |

\* As described in the policy at 42 CFR 412.4(f)(6)(iv), MS-DRGs that share the same base MS-DRG will all qualify under the special payment transfer policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

## BILLING CODE 4120-01-C

*B. Proposed Changes in the Inpatient Hospital Update for FY 2027*  
(§ 412.64(d))

1. Proposed FY 2027 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the “applicable percentage increase.” For FY 2027, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2026. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2027 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users

in accordance with section 1886(b)(3)(B)(ix) of the Act.

- An adjustment based on changes in economy-wide multifactor productivity (the productivity adjustment) in accordance with section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

As published in the FY 2006 IPPS final rule (70 FR 47403), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket of every 4 years. In compliance with section 404 of Public Law 108–173, in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36859 through 36866), we replaced the 2018 based IPPS operating and capital market baskets with the rebased and revised 2023-based IPPS operating and capital market baskets beginning in FY 2026. Consistent with our established frequency of rebasing the IPPS market basket every 4 years, we plan on proposing to rebase and revise the IPPS market in the FY 2030 IPPS/LTCH PPS proposed rule.

We are proposing to base the FY 2027 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.’s (IGI’s) fourth quarter 2025 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through third quarter 2025, which is estimated to be 3.2 percent. We are also proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate, to determine the FY 2027 market basket update in the final rule.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the

productivity adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The U.S. Department of Labor’s Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is published by BLS as private nonfarm business total factor productivity ((TFP) previously referred to as multifactor productivity).<sup>107</sup> Please see <https://www.bls.gov/productivity/> for the BLS historical published TFP data. A complete description of IGI’s TFP projection methodology is available on the CMS website at <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information>.

For FY 2027, we are proposing a productivity adjustment of 0.8 percent. Similar to the proposed market basket rate-of-increase, for this proposed rule, the estimate of the proposed FY 2027 productivity adjustment is based on IGI’s fourth quarter 2025 forecast. As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2027 productivity adjustment for the final rule.

Based on these data, we have determined four proposed applicable percentage increases to the standardized amount for FY 2027, as specified in the following table:

**TABLE V.B-01: PROPOSED FY 2027 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS**

| <b>FY 2027</b>                                                                                         | <b>Hospital Submitted Quality Data and is a Meaningful EHR User</b> | <b>Hospital Submitted Quality Data and is NOT a Meaningful EHR User</b> | <b>Hospital Did NOT Submit Quality Data and is a Meaningful EHR User</b> | <b>Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User</b> |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------|
| Proposed Market Basket Rate-of-Increase                                                                | 3.2                                                                 | 3.2                                                                     | 3.2                                                                      | 3.2                                                                          |
| Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act    | 0.0                                                                 | 0.0                                                                     | -0.8                                                                     | -0.8                                                                         |
| Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act | 0.0                                                                 | -2.4                                                                    | 0.0                                                                      | -2.4                                                                         |
| Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act                            | -0.8                                                                | -0.8                                                                    | -0.8                                                                     | -0.8                                                                         |
| <b>Proposed Applicable Percentage Increase Applied to Standardized Amount</b>                          | <b>2.4</b>                                                          | <b>0.0</b>                                                              | <b>1.6</b>                                                               | <b>-0.8</b>                                                                  |

<sup>107</sup> <https://www.bls.gov/productivity/notices/2021/mfp-to-tfp-term-change.htm>.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, reduced by a productivity adjustment.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act.

As discussed in section V.F. of the preamble of this proposed rule, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027. We refer readers to section V.F. of the preamble of this proposed rule for further discussion of the MDH program.

For FY 2027, we are proposing the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 2.4 percent for a hospital that submits quality data and is a meaningful EHR user (as defined in section 1886(n) of the Act); a proposed update of 0.0 percent for a hospital that submits quality data and is not a meaningful EHR user; a proposed update of 1.6 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and a proposed update of –0.8 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. As previously discussed, we are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket update and the productivity adjustment), we would use such data, if appropriate, to determine the market basket update and the

productivity adjustment in the final rule.

## 2. Proposed FY 2027 Puerto Rico Hospital Update

Section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have “three-quarters” of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for “subsection (d)” hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

For FY 2027, consistent with section 1886(b)(3)(B) of the Act, as amended by section 602 of Public Law 114–113, we are setting the applicable percentage increase for Puerto Rico hospitals by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS for Puerto Rico hospitals will be equal to the rate of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of three-quarters of the

applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for Puerto Rico hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to the productivity adjustment at section 1886(b)(3)(B)(xi) of the Act. As noted previously, section 1886(b)(3)(B)(xi) of the Act states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

Based on IGI’s fourth quarter 2025 forecast of the 2023-based IPPS market basket update with historical data through third quarter 2025, for this FY 2027 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we are proposing a market basket update of 3.2 percent reduced by a productivity adjustment of 0.8 percentage point. Therefore, for FY 2027, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that could be applied to the standardized amount. Based on these data, we determined the following proposed applicable percentage increases to the standardized amount for FY 2027 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we are proposing a FY 2027 applicable percentage increase to the operating standardized amount of 2.4 percent (that is, the FY 2027 estimate of the proposed market basket rate-of-increase of 3.2 percent, less 0.8 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we are proposing a FY 2027 applicable percentage increase to the operating standardized amount of 0.0 percent (that is, the FY 2027 estimate of the proposed market basket rate-of-increase of 3.2 percent, less 2.4 percentage points (the proposed market basket rate-of-increase of 3.2 percent  $\times$  0.75 for failure to be a meaningful EHR user), and less 0.8 percentage point for the proposed productivity adjustment).

As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2027 market basket update and the productivity adjustment for the FY 2027 IPPS/LTCH PPS final rule.

**TABLE V.B-02: PROPOSED FY 2027 APPLICABLE PERCENTAGE INCREASES FOR PUERTO RICO HOSPITALS UNDER THE IPPS**

| FY 2027                                                                                                | Hospital is a Meaningful EHR User | Hospital is NOT a Meaningful EHR User |
|--------------------------------------------------------------------------------------------------------|-----------------------------------|---------------------------------------|
| Proposed Market Basket Rate-of-Increase                                                                | 3.2                               | 3.2                                   |
| Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act | 0.0                               | -2.4                                  |
| Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act                            | -0.8                              | -0.8                                  |
| <b>Proposed Applicable Percentage Increase Applied to Standardized Amount</b>                          | <b>2.4</b>                        | <b>0.0</b>                            |

*C. Rural Referral Centers (RRCs) Annual Updates to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)*

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at 42 CFR 412.96 set forth the criteria that a hospital must meet to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33) states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997, IPPS final rule with comment period (62 FR 45999 through 46000), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the designation of their geographic area as urban. Subsequently, in the August 1, 2000, IPPS final rule (65 FR 47087), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of “urban” and “rural” specified in subpart D of 42 CFR part

412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (42 CFR 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to 42 CFR 412.96(c)(1) through (5) and the September 30, 1988, **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if the hospital's—

- CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- Number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45217), in light of the COVID–19 PHE, we amended the regulations at 42 CFR 412.96(h)(1) to provide for the use of the best available data rather than the latest available data in calculating the national and regional CMI criteria. We also amended the regulations at 42 CFR 412.96(c)(1) to indicate that the individual hospital's CMI value for discharges during the same Federal fiscal year used to compute the national and regional CMI values is used for purposes of determining whether a hospital qualifies for RRC classification. We also amended the regulations 42 CFR 412.96(i)(1) and (2), which describe the methodology for calculating the number of discharges criteria, to provide for the use of the best available data rather than the latest available or most recent data when

calculating the regional discharges for RRC classification.

**1. Case-Mix Index (CMI)**

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at 42 CFR 412.96(c)(1)(ii). The proposed national median CMI value for FY 2027 is based on the CMI values of all urban hospitals nationwide, and the proposed regional median CMI values for FY 2027 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in 42 CFR 413.75). These proposed values are based on discharges occurring during FY 2025 (October 1, 2024, through September 30, 2025), and include bills posted to CMS' records through December 2025. We believe that this is the best available data for use in calculating the proposed national and regional median CMI values and is consistent with our proposal to use the FY 2025 MedPAR claims data for FY 2027 ratesetting.

In this FY 2027 IPPS/LTCH PPS proposed rule, we are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2026, they must have a CMI value for FY 2025 that is at least—

- 1.7783 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in 42 CFR 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region are set forth in the following table. We intend to update the proposed CMI values in the FY 2027 IPPS/LTCH PPS final rule to reflect the updated FY 2025 MedPAR file, which contains data from additional bills received through March 2026.

| Region                                                 | Proposed Case-Mix Index Value |
|--------------------------------------------------------|-------------------------------|
| 1. New England (CT, ME, MA, NH, RI, VT)                | 1.4884                        |
| 2. Middle Atlantic (PA, NJ, NY)                        | 1.5588                        |
| 3. East North Central (IL, IN, MI, OH, WI)             | 1.6479                        |
| 4. West North Central (IA, KS, MN, MO, NE, ND, SD)     | 1.6839                        |
| 5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) | 1.633                         |
| 6. East South Central (AL, KY, MS, TN)                 | 1.567                         |
| 7. West South Central (AR, LA, OK, TX)                 | 1.7816                        |
| 8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)           | 1.79165                       |
| 9. Pacific (AK, CA, HI, OR, WA)                        | 1.7329                        |

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS-DRG-based payment.

## 2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the

national standard is set at 5,000 discharges. For FY 2027, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2024 (that is, October 1, 2023, through September 30, 2024), which are the latest cost report data available at the time this proposed rule was developed. We believe that this is the best available data for use in calculating the proposed median number of discharges by region and is consistent with our data proposal to use cost report data from cost reporting periods beginning during FY 2024 for FY 2027 ratesetting. Therefore, we are proposing that, in addition to meeting

other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2026, must have, as the number of discharges for its cost reporting period that began during FY 2024, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. We refer readers to the proposed number of discharges as set forth in the following table. We intend to update these numbers in the FY 2027 final rule based on the latest available cost report data.

| Region                                                 | Proposed Number of Discharges |
|--------------------------------------------------------|-------------------------------|
| 1. New England (CT, ME, MA, NH, RI, VT)                | 8,887                         |
| 2. Middle Atlantic (PA, NJ, NY)                        | 10,328                        |
| 3. East North Central (IL, IN, MI, OH, WI)             | 8,265                         |
| 4. West North Central (IA, KS, MN, MO, NE, ND, SD)     | 7,742                         |
| 5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) | 11,167                        |
| 6. East South Central (AL, KY, MS, TN)                 | 8,402                         |
| 7. West South Central (AR, LA, OK, TX)                 | 6,412                         |
| 8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)           | 8,410                         |
| 9. Pacific (AK, CA, HI, OR, WA)                        | 9,204                         |

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

### *D. Proposed Payment Adjustment for Low-Volume Hospitals (§ 412.101)*

#### 1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The low-volume hospital payment adjustment is implemented in the regulations at 42 CFR 412.101. The additional payment adjustment to a low-

volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act and is based on the per discharge amount paid to the qualifying hospital. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment. The payment adjustment for low-volume hospitals is not budget neutral.

As discussed in the FY 2026 IPPS/ LTCH PPS final rule (90 FR 36908

through 36912), section 2201 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4) extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS, that is, the modified definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12), through September 30, 2025. The Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37), enacted on November 12, 2025, provided an extension of those temporary changes to the qualifying criteria and payment adjustment methodology for certain low-volume

hospitals through January 30, 2026. Most recently, the Consolidated Appropriations Act, 2026 (Pub. L. 119–75), provided an extension of those temporary changes to the qualifying criteria and payment adjustment methodology for certain low-volume hospitals through FY 2026 and the

portion of fiscal year 2027 beginning on October 1, 2026, and ending on December 31, 2026. Absent further Congressional action, beginning January 1, 2027 the low-volume hospital qualifying criteria and payment adjustment revert to the statutory requirements that were in effect prior to

FY 2011, and the preexisting low-volume hospital payment adjustment methodology and qualifying criteria, as implemented in FY 2005 and discussed later in this section, resume. We discuss the payment policies for FY 2027 in sections V.D.2 and V.D.3. of the preamble of this proposed rule.

**TABLE V.D.-01: LOW-VOLUME HOSPITAL QUALIFYING CRITERIA AND PAYMENT ADJUSTMENT FOR FYs 2019 AND SUBSEQUENT FYs**

| Fiscal Years                                                                | Road Miles | Total Discharges | Payment Adjustment                                                                                                             |
|-----------------------------------------------------------------------------|------------|------------------|--------------------------------------------------------------------------------------------------------------------------------|
| 2019 through 2026 and the portion of 2027 from 10/1/2026 through 12/31/2026 | >15        | <= 500           | 0.25                                                                                                                           |
|                                                                             |            | > 500 < 3,800    | $0.25 - [0.25/3300] \times (\text{number of total discharges} - 500) = (95/3300) - (\text{number of total discharges}/13,200)$ |
| The portion of 2027 beginning on 1/1/2027 and 2028 and subsequent years     | >25        | < 200            | 0.25                                                                                                                           |

## 2. Extension of Temporary Changes to Low-Volume Hospital Payment Definition and Payment Adjustment Methodology and Conforming Changes to Regulations

As discussed previously, section 2201 of the Full-Year Continuing Appropriations and Extensions Act, 2025, extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment through September 30, 2025. Section 6201 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 further extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS for the portion of FY 2026 beginning on October 1, 2025, and ending on January 30, 2026. Most recently, section 6201 of the Consolidated Appropriations Act, 2026 extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment through FY 2026 and the portion of fiscal year 2027 beginning on October 1, 2026, and ending on December 31, 2026. We note the extension provided by the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 was addressed in Change Request 14341 (Transmittal 13564) and the extension provided by the Consolidated Appropriations Act, 2026 was addressed in Change Request 14415 (Transmittal 13703), issued March 26, 2026. For additional information, please refer to the transmittal R13564OTN and R13703OTN.

Under section 1886(d)(12)(C)(i) of the Act, as amended by the Consolidated Appropriations Act, 2026, for FYs 2019

through FY 2026 and the portion of FY 2027 beginning on October 1, 2026 and ending on December 31, 2026, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. In accordance with the existing regulations at § 412.101(a), we define the term “road miles” to mean “miles” as defined at § 412.92(c)(1). Under section 1886(d)(12)(D) of the Act, as amended, for discharges occurring in FYs 2019 through 2026 and the portion of FY 2027 beginning on October 1, 2026 and ending on December 31, 2026, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term “discharge” for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), we specified a continuous, linear sliding scale formula to determine the low volume payment adjustment, as reflected in the regulations at § 412.101(c)(3)(ii). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment

adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. For qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low-volume hospital payment adjustment is calculated using the formula at § 412.101(c)(3)(ii) (which is shown in the Table V.D.–01). For this purpose, the term “discharge” refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges). The hospital’s most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low volume payment adjustment in the current year (§ 412.101(b)(2)(iii)). The low-volume hospital payment adjustment for FYs 2019 through 2025 is set forth in the current regulations at § 412.101(c)(3).

In this proposed rule, we propose to make conforming changes to the regulation text in § 412.101 to reflect the extension of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals in accordance with provisions of the Consolidated Appropriations Act, 2026. Specifically, we propose to make conforming changes to paragraphs (b)(2)(iii) and (c)(3) introductory text of § 412.101 to reflect that the low-volume hospital payment adjustment policy in effect through FY 2026 and the portion of fiscal year 2027 beginning on October 1, 2026, and ending on December 31, 2026 is the same low-volume hospital payment adjustment policy in effect for FYs 2019 through 2025 (as described in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399) and in the FY 2026 IPPS/LTCH PPS final rule (90 FR

36908 through 36912)). In addition, in accordance with the provisions of the Consolidated Appropriations Act, 2026, we are proposing to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that beginning with the portion of fiscal year 2027 beginning on January 1, 2027, and ending on September 30, 2027, and for fiscal year 2028 and subsequent fiscal years, the low-volume hospital payment adjustment policy reverts back to the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010, as described in section V.D.3. of the preamble of this proposed rule. We further propose that if the temporary changes to the low-volume payment adjustment are extended through legislation beyond December 31, 2026, we would make the conforming changes to the regulations at § 412.101(b)(2)(i) and (iii) and (c)(1) and (3) to reflect any further extension.

### 3. Payment Adjustment for the Portion of FY 2027 Beginning on January 1, 2027 and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, as amended by the Consolidated Appropriations Act, 2026, beginning with FY 2027 discharges occurring on or after January 1, 2027 the low-volume hospital definition and payment adjustment methodology revert to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and subsequent legislation. Specifically, section 1886(d)(12)(B) of the Act requires, for discharges occurring in FYs 2005 through 2010 and for discharges occurring during the portion of FY 2027 beginning on or after January 1, 2027, and subsequent fiscal years, that the Secretary determine an applicable percentage increase for these low-volume hospitals based on the “empirical relationship” between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges. The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals.

Therefore, absent further Congressional action, effective for the portion of FY 2027 beginning on January 1, 2027, and ending on September 30, 2027, and for FY 2028 and subsequent fiscal years, under current policy at § 412.101(b), to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road

miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. For the portion of FY 2027 beginning on January 1, 2027 and for subsequent fiscal years, the statute specifies that a low-volume hospital must have less than 800 discharges during the fiscal year. However, as required by section 1886(d)(12)(B)(i) of the Act, the Secretary has developed an empirically justifiable payment adjustment based on the relationship, for IPPS hospitals with less than 800 discharges, between the additional incremental costs (if any) that are associated with a particular number of discharges. Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25 percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief for low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. (Under the policy we established in that same final rule, hospitals with between 200 and 799 discharges do not receive a low-volume hospital adjustment.)

As discussed previously, for FYs 2005 through 2010 and FY 2019 and subsequent years, the discharge determination is made based on the hospital’s number of total discharges, that is, Medicare and non-Medicare discharges. The hospital’s most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011 through 2018, we used the most recently available MedPAR data to determine the hospital’s Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years.

In addition to the discharge criterion, a hospital must also meet the mileage criterion to qualify for the low-volume payment adjustment. As specified by section 1886(d)(12)(C)(i) of the Act, a low-volume hospital must be more than 25 road miles (or 15 road miles for FYs 2011 through the portion of FY 2027 ending on December 31, 2026) from another subsection (d) hospital.

Accordingly, for the portion of FY 2027 beginning on January 1, 2027, and for subsequent fiscal years, in addition to the discharge criterion, the eligibility for the low-volume payment adjustment is also dependent upon the hospital meeting the mileage criterion at § 412.101(b)(2)(i), which specifies that a hospital must be located more than 25 road miles from the nearest subsection (d) hospital, consistent with section 1886(d)(12)(C)(i) of the Act. We define, at § 412.101(a), the term “road miles” to mean “miles” as defined at § 412.92(c)(1) (75 FR 50238 through 50275 and 50414). As previously noted, we propose to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that for the portion of FY 2027 beginning on January 1, 2027, and for subsequent fiscal years, the low-volume hospital payment adjustment policy is the same as that in effect for FYs 2005 through 2010.

### 4. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment for FY 2027

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking, most recently in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36908 through 36912), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)



As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and (iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital must refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

In addition to the discharge criterion, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in section 1886(d)(12)(C)(i) of the Act, which is codified at § 412.101(b)(2), for the fiscal year. To meet the mileage criterion to qualify for the low-volume hospital payment adjustment for the portion of FY 2027 beginning October 1, 2026 through December 31, 2026, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital, as reflected in proposed revised § 412.101(b)(2). Additionally, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for the portion of FY 2027 beginning January 1, 2027 through September 30, 2027, a hospital must be located more than 25 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term "road miles" to mean "miles" as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospital(s), location on a map, and distance from the hospital

requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2027, we propose that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Specifically, for the portion of FY 2027 beginning October 1, 2026 through December 31, 2026, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2026, in order for the low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2026. If a hospital's written request for low-volume hospital status for the portion of FY 2027 beginning October 1, 2026 through December 31, 2026 is received after September 1, 2026, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2027 discharges beginning October 1, 2026 through December 31, 2026, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

Additionally, we are proposing that a hospital must also submit a written request for low-volume hospital status

to its MAC that includes sufficient documentation to establish that the hospital continues to meet the applicable mileage and discharge criteria for the portion of FY 2027 beginning on January 1, 2027 through September 30, 2027 (as described earlier). Specifically, for the portion of FY 2027 beginning on January 1, 2027, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than December 1, 2026, in order for the 25-percent, low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after January 1, 2027. If a hospital's written request for low-volume hospital status for the portion of FY 2027 beginning on January 1, 2027 is received after December 1, 2026, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2027 discharges on or after January 1, 2027, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

A hospital may choose to make a single written request for low-volume hospital status to its MAC for both the portion of FY 2027 beginning on October 1, 2026 and ending December 31, 2026 and the portion of FY 2027 beginning on January 1, 2027 through September 30, 2027 by the September 1, 2026 deadline discussed previously. Alternatively, a hospital may choose to submit separate written requests, one for the portion of FY 2027 beginning on October 1, 2026 and ending on December 31, 2026 (by the September 1, 2026 deadline discussed previously), and another for the portion of FY 2027 beginning on January 1, 2027 through September 30, 2027 (by the December 1, 2026 deadline discussed previously).

Under this process, a hospital that qualified for the low-volume hospital payment adjustment for FY 2026 may continue to receive a low-volume hospital payment adjustment for FY 2027 without reapplying if it meets both the discharge criterion and the mileage criterion applicable for FY 2027 (that is, the discharge criterion and mileage criterion for the period beginning October 1, 2026 through December 31, 2026, as well as the discharge criterion and mileage criterion for the period beginning on January 1, 2027 through September 30, 2027, respectively). As discussed previously, for the portion of FY 2027 beginning on January 1, 2027, the discharge and the mileage criteria are reverting to the statutory requirements that were in effect prior to

FY 2011, and to the preexisting low-volume hospital qualifying criteria, as implemented in FY 2005 and specified in the existing regulations at § 412.101(b)(2)(i). As in previous years, we are proposing that such a hospital must send written verification that is received by its MAC no later than September 1, 2026 or December 1, 2026, respectively, stating that it meets the mileage criterion for the applicable portion(s) of FY 2027, as described previously. For example, for the portion of FY 2027 beginning October 1, 2026 through December 31, 2026, the hospital must state it is located more than 15 road miles from the nearest “subsection (d)” hospital. Similarly, for the portion of FY 2027 beginning on January 1, 2027, the hospital must state it is located more than 25 road miles from the nearest “subsection (d)” hospital. For FY 2027, we are further proposing that this written verification must also state, based upon the most recently submitted cost report, that the hospital meets the discharge criterion for the applicable portion(s) of FY 2027, as described previously. For example, for the portion of FY 2027 beginning October 1, 2026 through December 31, 2026, the hospital must have less than 3,800 discharges total, including both Medicare and non-Medicare discharges. Similarly, for the portion of FY 2027 beginning on January 1, 2027, the hospital must have less than 200 discharges total, including both Medicare and non-Medicare discharges. If a hospital’s request for low-volume hospital status for FY 2027 is received after September 1, 2026, (or after December 1, 2026 for the portion of FY 2027 beginning on January 1, 2027) and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume add-on payment adjustment to determine the payment for the hospital’s discharges for the applicable portion of FY 2027, effective prospectively within 30 days of the date of the MAC’s low-volume hospital status determination.

*E. Proposed Changes in the Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)*

**1. Background for the MDH Program**

Section 1886(d)(5)(G) of the Act provides special non-budget neutral payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). MDHs are paid for their hospital inpatient services based on the higher of the Federal rate or a blended rate based in part on the Federal rate and in part on the MDH’s hospital

specific rate. (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).) Under current law, the MDH program provisions at section 1886(d)(5)(G) of the Act will expire for discharges on or after January 1, 2027. Beginning with discharges occurring on or after January 1, 2027, absent further Congressional action, all hospitals that previously qualified for MDH status will be paid based on the Federal rate.

**2. Implementation of Legislative Extension of MDH Program**

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program has been extended by subsequent legislation, most recently through December 31, 2026 (that is, for discharges occurring before January 1, 2027), as discussed further in this section. (Additional information on the extensions of the MDH program through FY 2025 can be found in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36912).) As discussed in the FY 2026 IPPS/LTCH PPS final rule, the MDH program provision at section 1886(d)(5)(G) of the Act was set to expire at the end of FY 2025 (90 FR 36913). Subsequently, the MDH program was extended by additional legislation as follows:

- Section 6202 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37), enacted on November 12, 2025, provided for an extension of the MDH program through January 30, 2026.
- Section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75), enacted on February 3, 2026, provided for an extension of the MDH program through December 31, 2026 (that is, for discharges occurring before January 1, 2027).

Specifically, section 6202 of Public Law 119–75 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act by striking “January 31, 2026” and inserting “January 1, 2027”. Section 6202 of Public Law 119–75 also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act. Therefore, we are proposing to make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect the extension of the MDH program through December 31, 2026.

Generally, as a result of these extensions, a provider that was classified as an MDH as of September 30, 2025 may continue to be classified as a MDH as of October 1, 2025, with no need to reapply for MDH classification. (For more information on the MDH extensions through December 31, 2026, see Change Request 14341 (Transmittal 13564), issued December 23, 2025 and Change Request 14415 (Transmittal 13703), issued March 27, 2026, which are available online at <https://www.cms.gov/medicare/regulations-guidance/transmittals/2025-transmittals/r13564otn> and <https://www.cms.gov/medicare/regulations-guidance/transmittals/2026-transmittals/r13703otn>.

**3. Expiration of the MDH Program**

Because section 6202 of the Consolidated Appropriations Act, 2026 extended the MDH program through December 31, 2026 only, beginning January 1, 2027, the MDH program will no longer be in effect. Since the MDH program is not authorized by statute beyond December 31, 2026, absent Congressional action, beginning January 1, 2027, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the Federal rate.

When the MDH program was set to expire at the end of FY 2012, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405), we revised our sole community hospital (SCH) policies to allow MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions. We codified these changes in the regulations at § 412.92(b)(2)(i) and (v). For additional information, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53674). We note that a MDH that classifies as a SCH in anticipation of the MDH program expiration would have to reapply for MDH classification in accordance with the regulations at 42 CFR 412.108(b) and meet the classification criteria at 42 CFR 412.108(a) in the event that the MDH program is further extended, and the provider wishes to return to its classification as a MDH.

As noted, we are proposing to make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect the extension of the MDH program through December 31, 2026. We are further proposing that if the MDH program were to be extended by law beyond December 31, 2026, similar

to how it was extended by prior legislation as described previously, we would, depending on timing of such legislation in relation to the final rule, modify our proposed conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect any such further extension of the MDH program. These modifications to our proposed conforming changes would only be made if the MDH program were to be extended by statute beyond December 31, 2026.

*F. Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)*

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983, through September 30, 1984). The base year PRA is updated annually for inflation.

In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at non-provider sites, when applicable), and the hospital's Medicare share of total inpatient days. Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient

or outpatient departments of the IPPS hospital (and, for discharges occurring on or after October 1, 1997, at non-provider sites, when applicable) to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress established a limit on the number of allopathic and osteopathic residents that a hospital could include in its FTE resident count for direct GME and IME payment purposes in the Balanced Budget Act of 1997 (Pub. L. 105–33). Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME cannot exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

2. Proposed Requirements To Prohibit Unlawful Discrimination in Approved Medical Residency Programs

Hospitals may receive direct GME and IME payments for residents in “approved medical residency training programs.” Section 1886(h)(5)(A) of the Act defines an “approved medical residency training program” as “a residency or other postgraduate medical training program participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary.” “Approved medical residency program” and equivalent terms are defined in the regulations at §§ 412.105(f)(1)(i), 413.75(b), and 415.152. In general, under these regulations, an “approved” program is a program accredited by one of several national accrediting bodies or that leads toward board certification by the American Board of Medical Specialties (ABMS).

Therefore, to ensure that accreditation for approved medical residency

programs is in compliance with applicable laws related to race-based admission policies and to improve the accreditation process, in the CY 2026 OPPTS/ASC final rule (90 FR 54024 through 54027), we finalized changes to the regulations at §§ 412.105(f)(1)(i), 413.75(b), and 415.152, to state that accrediting organizations may not use accreditation criteria that promote or encourage discrimination on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. We also clarified that prohibited practices under this policy include all other conduct in violation of federal antidiscrimination laws, including any “unlawful practices” under the Attorney General's *Guidance for Recipients of Federal Funding Regarding Unlawful Discrimination* (July 29, 2025).

The policy finalized in the CY 2026 OPPTS/ASC final rule applied specifically to graduate medical education accrediting bodies. In this proposed rule, we are proposing a similar policy that would apply to approved medical residency programs themselves. Specifically, we are proposing to require that, in addition to meeting other applicable requirements, an approved medical residency training program must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. We believe such a policy is necessary to ensure that, even in the absence of discriminatory accreditation standards, individual programs do not implement policies that constitute unlawful discrimination under Federal law. The effective date of this proposed policy would be October 1, 2026.

In order to streamline the regulations text and ensure consistent application of the requirements to approved medical residency programs and GME accrediting organizations, we are also proposing to consolidate the majority of our existing and proposed non-discrimination requirements under proposed new 42 CFR 413.84. We are proposing to cross-reference this new section as necessary in the regulations at §§ 412.105(f)(1)(i), 413.75(b), and 415.152. We further note that we are

proposing conforming policies in section V.G.3. of this proposed rule with respect to approved nursing and allied health education programs under 42 CFR 413.85.

### 3. Proposed Modifications to the Criteria for New Residency Programs

#### a. Background

Section 1886(h)(4)(H)(i) of the Act requires CMS to establish rules for applying the direct GME cap in the case of medical residency training programs established on or after January 1, 1995. Under section 1886(d)(5)(B)(viii) of the Act, this provision also applies for purposes of the IME adjustment. These statutory requirements are implemented in the direct GME regulations at §§ 413.79(e)(1) through (3) and the IME regulations at § 412.105(f)(1)(vii), which provide for an FTE cap increase for certain hospitals that begin training residents in a new medical residency training program(s) on or after January 1, 1995, and specify the methodology for determining the permanent cap adjustment. Under these rules, cap adjustments are not provided for expansions of existing programs. Rather, a new urban teaching hospital receives a single five-year cap-building window to start new residency programs and grow those new residency programs, after which point its IME and DGME caps are permanently set. However, a rural teaching hospital may receive a separate cap adjustment each time it starts a new program. CMS originally implemented these policies in the August 29, 1997 **Federal Register** (62 FR 46005) and in the May 12, 1998 **Federal Register** (63 FR 26333); the calculation of both the DGME cap and IME cap for new programs is discussed in the August 31, 2012 **Federal Register** (77 FR 53416).

Section 413.79(l) defines a new medical residency training program as “a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.” In the August 27, 2009 **Federal Register** (74 FR 43908 through 43917), CMS clarified the definition of a “new” residency program and adopted supporting criteria regarding whether or not a residency program can be considered new for the purpose of determining if a hospital can receive additional direct GME and/or IME cap slots for that program. CMS adopted these criteria in part to prevent situations where a program at an existing teaching hospital might be transferred to a new teaching hospital, resulting in cap slots created for the

same program at two different hospitals. Under this policy, in addition to receiving initial accreditation, to be considered a “new” program for which new cap adjustments can be established, a residency program must satisfy three primary criteria (74 FR 43912):

- The program director is new; *and*
- The teaching staff are new; *and*
- The residents are new.

Over the years, we have received questions regarding the application of these criteria, such as whether CMS would still consider a program to be new for cap adjustment purposes if the three criteria are partially, but not fully, satisfied. We have answered such questions by stating that, generally, a residency program’s newness would not be compromised as long as the “overwhelming majority” of the residents and staff are not coming from previously existing programs in the same specialty.

#### b. The FY 2025 Proposed Rule

In the FY 2025 IPPS/LTCH PPS proposed rule (May 2, 2024; 89 FR 36221 through 36224), we noted that the question of what constitutes a “new” program eligible to receive additional Medicare-funded GME slots has taken on increasing significance in light of the ability of urban hospitals to reclassify as rural under 42 CFR 412.103 for IME payment purposes and thus to receive additional IME cap slots for any new program started, leading to significant increases in aggregate Medicare IME spending. We stated that, to continue to ensure that new cap slots are created appropriately, we ultimately would like to establish additional criteria through rulemaking for determining program newness. However, we indicated that we were not yet certain about some of the criteria that should be proposed. Accordingly, we issued a proposal regarding the threshold for determining whether the “overwhelming majority” of residents in a program are new and solicited public input on other topics via a Request for Information (RFI) (89 FR 36222).

With regard to the newness of residents, we proposed that, in order for a residency program to be considered new, at least 90 percent of the individual resident trainees (not FTEs) must not have previous training in the same specialty as the new program. If more than 10 percent of the trainees (not FTEs) transferred from another program at a different hospital/sponsor in the same specialty, even during their first year of training, we proposed that this would render the program as a whole (but not the entire hospital or its other new programs, if applicable) ineligible

for new cap slots. In addition, we stated that there may be certain challenges that are unique to small or rural-based programs in developing new residencies, and that meeting the proposed threshold of 90 percent of resident trainees with no previous training experience in the specialty may be more difficult for those programs. Accordingly, we solicited comment on what should be considered a “small” program and what percentage threshold or other approach regarding new resident trainees should be applied to these programs. We specifically sought comment on defining a small residency program as a program accredited for 16 or fewer resident positions.

For further detail regarding our proposal on the newness of residents, we direct readers to the discussion in the FY 2025 proposed rule at 89 FR 36222.

As stated previously, in the FY 2025 proposed rule we also issued a Request for Information on other aspects of the policy for determining program newness. In particular, we noted that it would be reasonable for a new residency program to seek to hire some experienced staff members, and we therefore solicited feedback on what an appropriate threshold should be for the percentage of faculty with no previous experience teaching in a program in the same specialty. We also solicited comment on whether it would be appropriate to define a certain period of time (for example, 10 years or 5 years) during which a faculty member or program director must not have been employed by another program in the same specialty in order to be considered “new.” Finally, we sought input on two additional scenarios that might have implications for determining the newness of a residency program: the sharing of certain clinical and didactic experiences among residents from different programs, which we referred to as “commingling”; and situations in which one hospital operates two (or more) programs in the same specialty.

For further details regarding the topics on which we solicited public comment, we direct readers to the discussion in the FY 2025 proposed rule at 89 FR 36222 through 36224.

#### c. The FY 2025 Final Rule

In the FY 2025 IPPS/LTCH PPS final rule (August 28, 2024; 89 FR 69377 through 69380), we published a summary of the comments we received in response to our proposal that, for a residency program to be considered new, at least 90 percent of the individual resident trainees (not FTEs) must not have previous training in the

same specialty as the new program. We explained that, given the lack of consensus on this issue, we would not be finalizing our proposal in that rule. Instead, we initiated another comment solicitation particularly focused on the criterion regarding newness of residents. As part of this request, we asked commenters to consider the broad statutory authority provided to the Secretary in this area, our prior rulemaking on this issue, and all of the public comments on our proposal as summarized in the final rule. In the interest of facilitating consensus, we encouraged commenters to provide feedback on which alternatives to their preferred approach they would consider most acceptable among those suggested by other commenters.

We also noted that, in response to our Requests for Information, the vast majority of commenters opposed any restrictions on the hiring of experienced faculty and program directors, as well as on the commingling of residents or sponsorship of multiple programs in the same specialty by a single hospital.

#### d. Summary of Responses to the Second Comment Solicitation

We received 14 timely pieces of correspondence to our second comment solicitation on an appropriate standard for determining the newness of residents in a new program, including potential exceptions for small and/or rural programs. In addition, commenters submitted additional feedback on other topics on which we had previously issued Requests for Information, including the hiring of experienced faculty and staff, commingling of residents, and sponsorship of multiple programs in the same specialty by a single hospital. Later in this section, we present a summary of the responses we received and discuss our proposed policy for determining whether a residency program should be considered new for purposes of receiving additional Medicare-funded GME slots.

Several commenters continued to urge CMS to define a “new” residency program as one that has received initial accreditation from the ACGME and to disregard other factors in determining program newness. However, a majority of commenters (including some who expressed a preference for the initial accreditation criterion) indicated that considering the previous training experience of residents could be an appropriate way for CMS to determine whether a residency program is genuinely new for cap-building purposes. Several commenters also indicated that the 90 percent threshold that we had originally proposed in the

FY 2025 IPPS/LTCH PPS proposed rule could be an acceptable standard, while urging CMS to provide exceptions for programs that fall short of the threshold as a result of various extenuating circumstances. (We discuss feedback pertaining specifically to exceptions for small and/or rural programs separately later in the section.)

For example, several commenters mentioned that hospitals sometimes need to replace residents who depart from a program for various reasons, including residents accepted via the supplemental match process who subsequently transfer to another residency in their preferred specialty. The commenters recommended that CMS allow programs to replace departing residents with other residents at the same training level, and that these replacements should not count against a program’s compliance with the 90 percent threshold. More generally, several commenters stated that the 90 percent requirement should apply only to residents at the Program Year 1 level, while residents recruited at the Program Year 2 level or above should not disqualify a program from consideration as “new.” In addition, a number of commenters recommended that CMS allow a program to demonstrate that it would have met the 90 percent threshold were it not for the results of the National Resident Matching Program (the “Match”) or other GME matching programs. Commenters noted that the results of the Match are binding on hospitals, and that selecting against candidates with prior training experience could violate the Match code of conduct and result in programs being banned from participation in the Match.

A few commenters indicated that, for purposes of determining whether a program complies with the minimum new resident threshold, CMS should consider all the individual residents that enter the program during its five-year cap-building period. Additionally, some commenters recommended that CMS conduct interim reviews during the cap-building period to determine whether a new program is on track to meet the requirements and to give providers a chance to make necessary changes before a final newness determination is made. Several commenters also indicated that residents with previous training experience could be excluded from the final cap calculation without disqualifying the program itself from consideration as new. One commenter suggested that, instead of establishing an overall new resident threshold, CMS should only limit the number of

residents admitted from the *same* existing program.

In general, commenters reiterated their strong opposition to any restrictions on the hiring of experienced faculty and program directors, stating that such a policy would be harmful to the development of new residency programs. However, some commenters suggested a compromise policy whereby CMS would consider the previous experience of faculty and program director in conjunction with the previous experience of residents. Under this policy, CMS would continue to assess newness primarily on the basis of the proportion of residents with previous experience training in a program in the same specialty, but would conduct an “enhanced review” under certain circumstances, as follows:

- 100 percent new residents: the program qualifies as new, without further review;
- At least 90 percent but less than 100 percent new residents: the program must demonstrate that residents have not previously trained in an existing residency program in the same specialty with any faculty or with the program director from the new residency program;
- Less than 90 percent new residents: the program does not qualify as new (subject to exceptions for certain categories of residents, as discussed previously).

The commenters stated that this policy would effectively prevent the transfer of existing programs without unduly restricting the ability of programs to hire experienced staff.

Other commenters recommended that CMS adopt a “safe harbor” policy, whereby a separately accredited program would be considered “new” regardless of any potential overlap (in terms of residents, faculty or program director) with an existing program, as long as the existing program remains in operation for at least one year. Commenters argued that the concurrent operation of both programs would make it clear that the new program does not constitute a relocation of the existing program or an inappropriate duplication of the existing program’s cap slots. Similarly, one commenter recommended that, instead of considering the previous experience of residents or staff, CMS should only consider whether these individuals are “solely committed” to the new program going forward.

Commenters agreed that CMS should create exceptions to the new requirements for small and/or rural programs. A majority of commenters also agreed that a “small” program

should be defined as one that is accredited for 16 or fewer resident positions, although a few commenters indicated that only small programs located in rural or urban underserved areas should qualify for an exception. (We note that one commenter recommended a higher ceiling of 22 resident positions.) The commenters recommended various more lenient newness criteria for programs that would qualify for an exception, with a few commenters recommending that such programs be exempted entirely from the newness requirements. In general, commenters urged CMS to ensure that the new program criteria do not unfairly disadvantage small programs or impede the development of residency programs in rural and/or urban underserved areas, with a few commenters also voicing particular concern about the effect of potential policies on Rural Track Programs.

Finally, commenters generally reiterated their opposition to any restrictions on “commingling” of residents or on hospitals sponsoring multiple residency programs in the same specialty. Commenters asserted the educational soundness of shared clinical and didactic experiences and indicated that such arrangements are increasingly required by the ACGME. In addition, commenters provided examples of circumstances under which a hospital might sponsor multiple programs in the same specialty, such as in the wake of a merger of hospitals, or in the case of a hospital that serves a large geographic area.

#### e. Proposal

We thank the commenters for their thoughtful feedback in response to the comment solicitation published in the FY 2025 IPPS final rule. While commenters continued to recommend various ways of defining a “new” residency program for purposes of establishing FTE caps, we believe there is sufficient consensus on the major issues for us to propose certain modifications to our existing policy.

#### (1) Initial Accreditation

First, we acknowledge that a number of commenters continued to urge CMS to define a new residency program as one that has received initial accreditation from the ACGME and to disregard other factors in determining program newness. While we concede that this approach would be simple administratively, we reiterate the concerns that we originally discussed in the August 27, 2009 **Federal Register**, where we explained that the mission and priorities of CMS differ from those

of the accrediting bodies, and that, in determining whether a residency program is genuinely new, it is appropriate for CMS to consider factors in addition to the accrediting body’s characterization of that program (see discussion at 74 FR 43909 through 43913). In particular, we emphasize that a primary concern of CMS, not shared by the accrediting bodies, remains the inappropriate duplication of FTE cap slots associated with the relocation of an existing program from one hospital to another. Thus, although the existing regulations at § 413.79(l) refer to initial accreditation as one of the criteria for determining whether a program is genuinely new for cap-building purposes, we continue to believe that we cannot rely solely on the characterization of an accrediting body in making this determination.

#### (2) Proposed Removal of Restrictions on Experienced Faculty and Staff

Nevertheless, we are persuaded by commenters’ arguments that some of the supporting factors promulgated in the August 27, 2009 **Federal Register** may be overly restrictive. In particular, we are persuaded by commenters who argued that CMS should not restrict the ability of new residency programs to hire experienced faculty and program directors. After considering the feedback we received in response to our original Requests for Information and our subsequent comment solicitation, we believe that considering the previous training experience of residents (as discussed in more detail later in this section) should provide a sufficient guardrail to ensure that existing programs are not being transferred between hospitals. Thus, we are proposing that, effective for programs started on or after October 1, 2026, we would no longer consider the previous employment of the faculty or program director in determining whether a residency program should be considered genuinely new for cap-building purposes. That is, a hospital would no longer have to demonstrate that the faculty and program director in a new program have not previously been employed in an existing program in the same specialty. We note that programs started on an earlier date that are still within the five-year cap-building period as of October 1, 2026, would continue to be subject to the newness criteria established in the August 27, 2009 **Federal Register**.

#### (3) Proposed Requirement for New Residents

While we are proposing to remove the requirement related to previous

employment of the faculty or program director, we do believe it is still appropriate for CMS to consider the previous training experience of residents in determining whether a residency program should be considered genuinely new. As discussed previously in the summary of responses to our second comment solicitation, a majority of commenters indicated that a 90 percent threshold could be an appropriate standard for determining whether the “overwhelming majority” of residents in a program are in fact new. Additionally, as discussed in the FY 2025 IPPS proposed rule (89 FR 36222), a 90 percent threshold would be generally consistent with the concept of an “overwhelming majority,” and we have precedent for such a threshold in the regulations for section 5506 of the Affordable Care Act, which state that a hospital is considered to have taken over an “entire” program from a closed hospital if it can demonstrate that it took in 90 percent or more of the FTE residents in that program. Therefore, we are proposing that, effective for programs started on or after October 1, 2026, in order for a residency program to be considered new, in addition to receiving initial accreditation from the appropriate accrediting body, at least 90 percent of the individual resident trainees (not FTEs) must not have previous training in the same specialty as the new program. Apart from the exceptions, discussed later in this section, for small programs, for certain residents admitted via a binding resident matching program, and for displaced residents counted under the provisions of 42 CFR 413.79(h), this proposal regarding the newness of residents is substantially the same as the policy we had originally proposed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36222).

For example, if a hospital establishes a new residency program in internal medicine, then, under our proposal, at least 90 percent of the residents in that program must not have previous training experience in another internal medicine program. If a resident was formally enrolled in another internal medicine program (whether preliminary or categorical), even if that resident switched programs during their first year of training, we would consider that resident to have previous training in the same specialty. By contrast, if an individual previously trained in a specialty *other* than internal medicine, and that resident switched into the new internal medicine program and began training in that program as a first-year resident, then the resident would *not* be

considered to have previous training in the same specialty, and would be counted as a new resident for purposes of determining compliance with the 90 percent threshold.

(Consistent with the definition of “resident” at 42 CFR 413.75(b), in the example noted previously we are distinguishing between a resident that was actually accepted, enrolled and participated in an internal medicine residency program from a resident who was *not* enrolled in an internal medicine program but who may have done a rotation in internal medicine as part of the requirements for a different specialty. Additionally, we note that an individual who enters a subspecialty training program, after having previously completed a residency in the antecedent specialty, would be counted as a new resident—for example, a resident who enters a critical care medicine fellowship after having previously completed a residency program in internal medicine would be counted as a new resident under our proposal.)

Under the proposed policy, we would determine whether a program has satisfied the 90 percent threshold by tallying all of the individual residents who enter a program during the five-year cap building period (that is, for new urban teaching hospitals, during the first five program years of the first new program’s existence; and for rural hospitals, during the first five program years of each new program). For example, if 50 trainees (not FTEs) enter the program over the course of the five-year cap building period, then at least 45 of the trainees (that is, 90 percent of 50) must enter the program as brand-new first-year residents in that particular specialty. If more than 10 percent of the individual trainees (not FTEs) previously trained in another program in the same specialty, we propose that this would render the program not new and therefore ineligible for an FTE cap adjustment. We would apply standard rounding in instances where the quotient does not equal a whole number, rounding down to the nearest whole number when the remainder is less than 0.5, and rounding up to the nearest whole number when the remainder is greater than or equal to 0.5. For example, if 48 trainees (not FTEs) enter a program over the course of the five-year cap building period, then at least 43 of the trainees (90 percent of 48 = 43.2, which rounds down to 43) must not have previous experience training in a different program in the same specialty.

We propose that, after the end of the five-year cap building period, the MAC

would review the previous training experience of each individual trainee and determine the newness of the residency program prior to calculating the IME and DGME cap adjustments for the hospital. Consistent with our historical policy, the MAC would not be required to provide an initial assessment of “newness” prior to the end of the five-year cap building period.

#### (4) Proposed Exceptions for Certain Categories of Residents

As noted previously, we are proposing to create a limited exception to the counting rules for certain residents admitted via the National Resident Matching Program (the Match) or other third-party resident matching programs whose results are binding on hospitals. (Examples of other matching programs that would fall under this provision include the Supplemental Offer and Acceptance Program, the Urology Residency Match Program, and the SF Match for Ophthalmology and Plastic Surgery residency programs.) Based on feedback received from commenters, we understand that the Match and similar programs are generally used to match prospective first-year residents to residency programs in their chosen specialties, and that hospitals do not have the discretion to refuse admission to a resident matched via this process. We also understand that candidates applying through the various matching programs may occasionally have previous experience training in another program in the same specialty—for example, an individual who may have withdrawn from a residency program and is seeking to restart his or her training.

While hospitals may rank their preferred candidates, they cannot predict the ultimate complement of first-year residents allocated via the Match or other matching programs. As a result, a hospital that included multiple candidates with previous training experience on its ranked list could be required to accept a mix of residents that would cause it to fall short of our proposed 90 percent requirement. We agree with commenters that in such situations hospitals should not be penalized for the results of the Match or other binding resident matching programs. Accordingly, for purposes of determining compliance with the 90 percent requirement, we are proposing to exclude from the count of trainees any individuals with previous experience training in another program in the same specialty who enter the new program as first-year residents through the National Resident Matching Program

or another binding third-party resident matching program. That is, *such individuals would be excluded both from the numerator and from the denominator of the calculation used to determine the proportion of new vs. experienced residents.* However, assuming that the program otherwise satisfies the proposed 90 percent threshold, the hospital would report such individuals on the new resident lines of the hospital cost report (that is, lines 15 and 15.01 of Worksheet E–4 and line 16 of Worksheet E, Part A) and the individuals would be included in the calculation of the hospital’s permanent cap adjustment at the conclusion of the five-year cap-building period.

We also propose to exclude from the count of trainees any residents admitted into the new program from another program in the same specialty who meet the definition of a “displaced resident” under 42 CFR 413.79(h)(1)(iii). That is, *such individuals would be excluded both from the numerator and from the denominator of the calculation used to determine the proportion of new vs. experienced residents.* In order to prevent the inappropriate duplication of cap slots associated with a closed program or closed hospital, we propose that displaced residents must not be reported on the new resident lines or included in the hospital’s permanent cap adjustment. Instead, such individuals would be reported on the displaced resident lines (lines 16 and 16.01 of Worksheet E–4 and line 17 of Worksheet E, Part A) if the hospital qualifies for a temporary cap adjustment under 42 CFR 413.79(h). Otherwise, the individuals must be reported on the regular FTE lines (line 6 of Worksheet E–4 and line 10 of Worksheet E, Part A), subject to the hospital’s existing DGME and IME FTE caps. Furthermore, since rotation schedules, and not cost report entries, are used to identify individual residents training in the new program for the purpose of calculating the permanent cap at the end of the five year cap building period under 42 CFR 413.79(e)(1)(i)(A), the displaced residents listed on the rotation schedule would be excluded from the new program cap calculation. We note that under certain circumstances, if a hospital trains residents displaced by a hospital closure, it may receive priority for receipt of cap slots if it submits an application for a permanent cap adjustment under the provisions of section 5506.

For example, suppose that 50 individual trainees (not FTEs) enter a program during the five-year cap-building period, and that 4 of those



individuals enter the program as first-year residents via the Match and have previous experience training in another program in the same specialty. Additionally, the program admits 2 residents displaced from a closed program in the same specialty. If all 50 residents were included in the count, then at least 6 out of 50 or 12 percent of the residents in the program would be considered not new, rendering the program as a whole not new under our proposed 90 percent threshold. Under the proposed exceptions, we would exclude from this calculation the 4 first-year residents with previous training experience admitted via the Match, as well as the 2 residents displaced from the closed program. Thus, the hospital would have to demonstrate that at least 90 percent of the remaining 44 residents (that is,  $39.6 \approx 40$  residents) do not have previous experience training in another program in the same specialty. During the initial years of the new program, the hospital would report the 4 first-year residents on the new program lines, while it would report the 2 displaced residents on the displaced resident lines or the regular FTE lines, as applicable. At the conclusion of the cap-building period, the calculation of the hospital's permanent cap adjustment would include the 4 first-year residents admitted via the Match and exclude the 2 residents displaced from the closed program.

#### (5) Proposed Exception for Small Programs

In addition, we are proposing to create an exception to the 90 percent requirement for small residency programs. We propose to define a "small" program as one that is accredited for 16 or fewer resident (or fellow) positions, regardless of whether the program is located in an urban or a rural area. Based on the feedback we received from commenters, we believe that small programs, in particular, are at the greatest risk of failing to meet the 90 percent threshold for reasons beyond their control. Accordingly, we are proposing to exempt small residency programs, as defined previously, from the requirement that at least 90 percent of the residents who enter the program during the five-year cap-building period must not have previous experience training in another program in the same specialty. We are not proposing any minimum proportion of new residents that a small program must achieve in order to be considered new for cap-building purposes. However, programs accredited for 16 or fewer positions must still obtain initial accreditation from the appropriate accrediting body.

We note that we are not proposing to adopt various other exceptions or policies recommended by commenters, as summarized in the preceding section of this preamble. We believe that the criterion we have proposed would accomplish our stated goal of preventing the inappropriate duplication of FTE cap slots, while the exception for small programs provides a reasonable safeguard for those programs that are at greatest risk of failing to meet the proposed requirement for reasons beyond their control. Additionally, we believe that the proposed policies have the advantage of being unambiguous and administratively simple, whereas we wish to avoid scenarios in which CMS or the MACs would need to review individual hospitals' circumstances on a case-by-case basis.

Additionally, we note that we are not proposing any distinct policies with respect to the commingling of residents. Rather, we propose that program newness should be determined consistently on the basis of initial accreditation and the 90 percent new resident threshold. That is, we propose that if a particular program has received initial accreditation, and at least 90 percent of the individual trainees (not FTEs) entering the program during the five-year cap building period are new (with exceptions as noted previously), then the program would be considered new for cap-building purposes regardless of whether residents in that program have shared educational experiences with residents of an existing program in the same specialty.

Similarly, with regard to the question of whether it is permissible for one hospital to operate two or more programs in the same specialty, we propose that this would be permissible for cap-building purposes if the second or subsequent program has separately received initial accreditation and at least 90 percent of the individual trainees (not FTEs) entering the program during the five-year cap building period are new (with exceptions as noted previously). Note that this would be a change from existing policy, under which it is permissible for one hospital to operate two or more programs in the same specialty provided that the programs have separate program directors, staff, and separately matched residents without meeting any additional requirements (see discussion of existing policy in the August 27, 2009 **Federal Register** at 74 FR 43913).

In summary, we are proposing that, in addition to receiving initial accreditation by the appropriate accrediting body, for a residency program to be considered new, at least

90 percent of the individual resident trainees (not FTEs) must not have previous experience training in another program in the same specialty. We would no longer consider the previous employment of the faculty or program director in determining whether a residency program is genuinely new for cap-building purposes. We would determine compliance with the 90 percent threshold by tallying all of the individual residents who enter a program during the five-year cap building period (that is, for new urban teaching hospitals, during the first five program years of the first new program's existence; and for rural hospitals, during the first five program years of each new program). This tally would exclude individuals with previous experience training in another program in the same specialty who enter the new program as first-year residents through the National Resident Matching Program or another binding third-party resident matching program, as well as individuals who meet the definition of a "displaced resident" under 42 CFR 413.79(h)(1)(iii). The requirement that at least 90 percent of the individual residents must be new would not apply to small programs, defined as programs accredited for 16 or fewer resident positions, regardless of geographic designation. These policies would be effective for programs starting on or after October 1, 2026.

To ensure that the regulations text appropriately reflects our proposed policy, we propose to revise the text of 42 CFR 413.79(l) to state that a new medical residency training program means a program that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995, and that meets the following conditions:

- Subject to the following provisions, effective for programs started on or after October 1, 2026, at least 90 percent of the individual residents (not FTEs) that enter the program during the five-year cap building period (that is, for new urban teaching hospitals, during the first five program years of the first new program's existence under § 413.79(e)(1); and for rural hospitals, during the first five program years of each new program under § 413.79(e)(3)) must not have previous experience training in another program in the same specialty.

- For purposes of determining compliance with the preceding requirement, the count of individual residents excludes individuals with previous experience training in another program in the same specialty who enter the program as first-year residents through the National Resident Matching



Program or another binding third-party resident matching program.

- The 90 percent new resident requirement does not apply to a program accredited for 16 or fewer resident positions.

#### 4. Calculation of Direct GME and IME Payments Following a Merger of Hospitals

When a hospital merger involves one or more teaching hospitals, the surviving provider experiences an influx of FTE residents from the terminating providers' residency programs. The surviving hospital also absorbs those providers' FTE caps (63 FR 26329) and receives a merged per resident amount for purposes of direct GME payment (71 FR 48073). In addition, the Medicare Part A and Medicare Advantage (MA) patient loads of the surviving hospital represent the combined Medicare utilization of all hospitals (teaching and non-teaching) participating in the merger.

The surviving provider also experiences changes in the payment rates that determine the amount of its indirect medical education adjustment. In addition to the influx of FTE residents from the terminating providers' residency programs, the surviving provider absorbs those hospitals' existing IME FTE caps and available beds, resulting in a change to its intern- and resident-to-bed (IRB) ratio. The total amount of IME payment is also affected by the combination of the merged hospitals' Part A and simulated MA DRG revenues.

While we are not proposing any new policies at this time, we are taking the opportunity to clarify in rulemaking the methodology for calculating DGME and IME payments for the surviving provider following a merger of hospitals. We discuss the procedure for calculating each payment type separately later in this section.

##### a. Calculating DGME Payments Following a Merger of Hospitals

If the surviving hospital begins a new cost reporting period effective with the date of the merger, then direct GME payment for that initial merged period and subsequent periods is determined based on the hospital's new, combined DGME payment rates (with special consideration for the rolling average during the first two cost reporting periods, as discussed further later in this section). However, if the merger takes place in the middle of the surviving hospital's cost reporting period, then the hospital's DGME payment for that period must reflect the

different payment rates that apply before and after the merger.

In the August 18, 2006 **Federal Register** (71 FR 48075–48076), we stated that direct GME payment for the surviving hospital would be calculated on the basis of two distinct sets of PRAs (that is, two distinct primary care PRAs and two distinct nonprimary care PRAs, or two distinct single PRAs, as applicable), one for the pre-merger period and one for the post-merger period. Thus, to calculate the DGME payment for the surviving hospital for the cost reporting period in which the merger occurred, the Medicare administrative contractor (MAC) performs a series of off-the-cost-report calculations, treating the pre-merger and post-merger periods of the surviving hospital's cost reporting period as if they were two short cost reporting periods. The MAC would calculate the direct GME payment for the surviving hospital for the portion of the cost reporting period prior to the merger using only the surviving hospital's FTE counts, PRA(s) and Medicare utilization rate. Separately, the MAC would calculate the surviving hospital's post-merger direct GME payment using the merged weighted average PRA(s) updated using special CPI–U factors; a combined rolling average FTE count reflecting the merged hospitals' FTE counts; and a combined Medicare utilization rate reflecting the portion of the cost reporting period following the merger. The MAC would add the pre-merger and post-merger payments to determine the surviving hospital's total reimbursement for that cost reporting period. We also stated in the 2006 rule that similar pre-merger and post-merger calculations are performed for the intern- and resident-to-bed ratio for purposes of IME payment, as discussed later in this preamble.

In effect, the pre- and post-merger timeframes are treated as though they were individual short cost reporting periods, with virtual payment rates established for each period on the basis of the best available data for all providers. Later in this section, we provide a detailed step-by-step explanation, with an illustrative example, of how to calculate pre- and post-merger direct GME payments according to the policy outlined previously.

To facilitate the calculation of the DGME payment amounts, the MAC determines the following variables separately for the pre- and post-merger timeframes, consistent with the FTE counting rules for non-12-month cost reporting periods as clarified in the August 4, 2025 **Federal Register** (90 FR

36915). In general, the pre-merger payment rates are based on data from the surviving provider only, while post-merger rates utilize data from all participating hospitals:

- *FTE resident count*—*Calculate separately for the pre-merger and post-merger periods:* To determine the partial year unweighted DGME FTE counts, the sum of allowable rotations for all residents during each period is divided by 365 or 366, using data from the master rotation schedule or a similar source (see 90 FR 36915–16 for further details). The weighted counts are obtained by applying the appropriate weighting factor to the rotations associated with each resident, and separate weighted counts are determined for primary care and non-primary care residents. For the pre-merger period, the count includes rotations allowable to the surviving provider only; for the post-merger period, the count includes the sum of all rotations allowable to the merged entity.<sup>108</sup>

- *FTE resident limit (cap)*—*Calculate separately for the pre-merger and post-merger periods:* The partial year DGME FTE resident limit is calculated by prorating the hospitals' original FTE caps, including any applicable adjustments, for the number of days in each respective period: the pre-merger limit is derived from the FTE caps of the surviving provider only, whereas the post-merger limit includes the combined caps of all hospitals participating in the merger. The prorated FTE caps are applied to the partial year FTE resident counts according to the usual procedure as described in the August 4, 2025 **Federal Register** (90 FR 36917). If any of the merged hospitals has residents participating in a rural track program or residents counted under section 422 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, codified at section 1886(h)(7) of the Act), then those counts and caps are also determined and applied separately for the pre- and post-merger periods.

- *Rolling average FTE count*—*Calculate separately for the pre-merger and post-merger periods:* The current, prior- and penultimate-year weighted FTE counts, which serve as the inputs to the three-year rolling average, must also be determined separately for the

<sup>108</sup> If any of the merged hospitals is training displaced residents or residents in the initial years of a new program, those weighted counts would be determined according to the same procedure and the FTEs would be added to the respective rolling averages calculated for the pre- and post-merger periods.

pre- and post-merger timeframes. The current year FTE counts are calculated as explained previously, while the prior- and penultimate-year counts are obtained from lines 12 and 13 of Worksheet E-4 of the respective hospitals' cost reports, and prorated according to the procedure described in the August 4, 2025 **Federal Register** (90 FR 36917).<sup>109</sup> The numerator of the rolling average for the pre-merger period consists of the prorated FTE counts of the surviving provider only, while the post-merger numerator equals the sum of the prorated FTE counts of the surviving and terminating providers, simulating what the effect of the merger would have been during the prior and penultimate cost reporting periods.

Note that a "virtual" rolling average must also be calculated for the merged provider's first two cost reporting periods beginning on or after the effective date of the merger: that is, the surviving and terminating providers' FTE counts must be combined as though they were merged during the prior and/or penultimate years (with proration applied as necessary to account for differences in the length of the respective hospitals' cost years). This procedure applies whether or not the merger occurred in the middle of the surviving provider's cost reporting period. Standard computation of the rolling average would resume in the third full post-merger cost reporting period.

In addition to the FTE resident count, FTE resident limit, and rolling average FTE count, the MAC also determines separate per resident amounts and Medicare patient loads (for both Part A and managed care enrollees) for the pre- and post-merger timeframes:

- *Per resident amount—Calculate separately for the pre-merger and post-merger periods:* Direct GME payment for the pre-merger period is calculated using the surviving provider's original

primary care and nonprimary care PRAs, or single PRA, as applicable, updated to the midpoint of the pre-merger period. The post-merger payment is calculated using the merged primary care and nonprimary care PRAs, or merged single PRA, as applicable, determined according to the procedure finalized in the August 18, 2006 **Federal Register** (71 FR 48075-6); the merged PRA(s) is updated for inflation to the midpoint of the post-merger period.

If the surviving and/or terminating providers count additional residents under the provisions of section 422, then direct GME payments for those residents would be calculated separately for the pre- and post-merger periods, as applicable, with the special per resident amounts updated according to the same procedures outlined previously.

- *Medicare patient load—Calculate separately for the pre-merger and post-merger periods:* Separate Medicare Part A and MA patient loads are determined for the pre- and post-merger periods using data from the hospitals' Provider Statistical and Reimbursement (PS&R) reports (see specific fields in the example table later in this section). For the pre-merger period, the numerator and denominator of the Medicare patient load comprise the Medicare and total inpatient days, respectively, attributable to the surviving provider during that period; for the post-merger period, the numerator and denominator comprise the sum of all inpatient days attributable to the merged hospitals (including any non-teaching hospitals absorbed by the surviving provider).

If either the pre- or post-merger period straddles multiple calendar years, then separate MA patient loads must also be determined for the portions of that period occurring prior to and on or after January 1, so that the MA DGME payments may be adjusted by the percentage reduction applicable to each calendar year (as required by the regulations at § 413.76(d)).

Since the cost report does not support the use of multiple DGME payment rates for portions of a single cost year, these

calculations must be performed off the cost report, and the results are summed to determine total DGME payment for the cost reporting period. Placeholder values based on the combined payment rates of the merged hospitals are reported as necessary on the applicable lines of Worksheet E-4.<sup>110</sup>

The following example illustrates the application of the policies described previously.

*Example:*

Consider a merger between teaching Hospitals A and B, effective November 1, 2023, where Hospital A is the surviving provider. Prior to the merger, Hospitals A and B had fiscal year ends of June 30 and December 31, respectively. As the surviving provider, Hospital A elects to maintain its existing fiscal year, and files a cost report for the period July 1, 2023, to June 30, 2024. Since different payment rates apply to the timeframes 07/01/23–10/31/23 and 11/01/23–06/30/24, two separate direct GME payments must be calculated for Hospital A's cost reporting period ending June 30, 2024. These calculations are performed off the cost report, and the sum of the total payments is reported on line 31 of Worksheet E-4 of the hospital cost report (Form CMS-2552-10). (Hospital B would file a terminating cost report for the period January 1, 2023–October 31, 2023, with direct GME payment determined in accordance with the rules applicable to short cost reporting periods, as clarified in the August 4, 2025 **Federal Register**.)

The following table summarizes the data that will be used to calculate Hospital A's pre- and post-merger DGME payments, based on the surviving and terminating providers' historical cost reports, as well as other sources such as rotation schedules and PS&R reports:

<sup>109</sup> Note that the proration factor is applied *after* the prior- and penultimate-year FTE counts have been determined based on data from the respective cost reports, consistent with the instructions to lines 12 and 13 of Worksheet E-4.

<sup>110</sup> For example, the FTE caps and adjustments of the surviving and terminating providers would be added and reported on the applicable FTE cap lines as though the providers had been merged for the entire cost reporting period.

| Data Point                                                 | Hospital A  | Hospital B | Source                                     |
|------------------------------------------------------------|-------------|------------|--------------------------------------------|
| DGME FTE resident count (weighted): 1/1/23 – 6/30/23       | [not shown] | [9.75]     | Rotation schedule or similar documentation |
| DGME FTE resident count (weighted): 7/1/23 – 10/31/23      | 14.28       | [6.80]     | Rotation schedule or similar documentation |
| DGME FTE resident count (weighted): 11/1/23 – 6/30/24      | 27.72       | 13.20      | Rotation schedule or similar documentation |
| Prior year weighted DGME FTE resident count                | 40.00       | 21.50      | Cost report data                           |
| Penultimate year weighted DGME FTE resident count          | 39.00       | 19.25      | Cost report data                           |
| DGME FTE resident limit (including applicable adjustments) | 40.00       | 25.00      | Cost report data                           |
| Per resident amount (single PRA)                           | \$134,000   | \$127,500  | Cost report data <sup>111</sup>            |
| Part A inpatient days: 7/1/23 – 10/31/23                   | 8,303       | [6,888]    | PS&R report type 110                       |
| Part A inpatient days: 11/1/23 – 6/30/24                   | 16,335      | 13,552     | PS&R report type 110                       |
| MA inpatient days: 7/1/23 – 10/31/23                       | 2,768       | [3,936]    | PS&R report type 118                       |
| MA inpatient days: 11/1/23 – 12/31/23                      | 1,373       | 1,952      | PS&R report type 118                       |
| MA inpatient days: 1/1/24 – 6/30/24                        | 4,073       | 5,492      | PS&R report type 118                       |
| Total inpatient days: 7/1/23 – 10/31/23                    | 18,450      | [19,680]   | Hospital census data                       |
| Total inpatient days: 11/1/23 – 6/30/24                    | 36,300      | 38,420     | Hospital census data                       |
| MA DGME percent reduction: CY 2023                         |             | 2.74%      | FY 2025 IPPS final rule (89 FR 69384)      |
| MA DGME percent reduction: CY 2024                         |             | 2.33%      | FY 2026 IPPS final rule (90 FR 36919)      |

**Notes:**

• Since the hospitals are merged effective November 1, 2023, Hospital B technically does not have a separate FTE resident count, or separate inpatient days, during the period 11/01/23–06/30/24; post-merger data for Hospital B are broken out for illustrative purposes only. In addition, Hospital B's pre-merger FTE counts and inpatient days for its 2023 cost year are printed in brackets since they do not factor into the merged provider's DGME payment rates for FYE 06/30/24. (However, note that Hospital B's pre-merger FTE counts will be used to calculate the rolling average for the merged provider's subsequent cost reports, as explained further later in this section.) Hospital B would file its terminating cost report and receive DGME payment for the period 01/01/23–10/31/23 in accordance with the rules applicable to short cost reporting periods.

As shown later in this section, we assume in this example that Hospitals A and B each have a single PRA; accordingly, the FTE counts in this table represent combined totals for residents in both primary and nonprimary care programs.

• The prior- and penultimate-year FTE counts are required to calculate the three-year rolling averages for the pre- and post-merger periods. Hospital A's prior- and penultimate-year cost reporting periods are those ending on June 30, 2023, and June 30, 2022, respectively; Hospital B's are those ending on December 31, 2022, and December 31, 2021.

• The hospitals' DGME FTE resident limits include any applicable adjustments, such as those for new programs or slots received under various statutory provisions. For the purpose of this example, we assume that neither hospital has received additional residency slots under section 422.

• Consistent with the policy finalized in the August 18, 2006 **Federal Register** (71 FR 48075), the individual hospitals' original (pre-merger) PRAs are sourced from the most recently settled cost reports. In this example we assume that the most recently settled cost reports of Hospitals A and B are those ending on June 30, 2021, and December 31, 2020, respectively. For the sake of convenience, we assume each hospital has a single PRA applicable to residents in all specialties.

• Managed care and total inpatient days during the post-merger period 11/01/23–06/30/24 are further broken out into portions occurring before and after January 1, since different percentage reductions to MA DGME payments apply to calendar years 2023 and 2024.

Pre-Merger Direct GME Payment (July 1, 2023, to October 31, 2023)

To calculate the surviving provider's direct GME payment for the pre-merger period 07/01/23–10/31/23, the following variables are determined based on Hospital A's individual records for the relevant timeframe:

• **FTE resident count:** As indicated in the table outlined previously, Hospital A's weighted DGME FTE resident count during the period 07/01/23–10/31/23 is 14.28 FTEs, based on data from Hospital A's rotation schedules or similar documentation and determined

according to the methodology clarified in the August 4, 2025 **Federal Register**.

• **FTE resident limit:** The FTE resident limit for the pre-merger period is obtained by prorating Hospital A's full-year DGME FTE cap. Since there are 123 days during the period 07/01/23–10/31/23 and the full cost reporting period includes February 29, the prorated FTE cap equals:  $40 \times (123 \div 366) = 13.44$ , which is less than the actual weighted DGME count of 14.28. Accordingly, Hospital A's effective DGME resident count for the pre-merger period is 13.44 FTEs.

• **Rolling average FTE count:** To determine the three-year rolling average, Hospital A's prior- and penultimate-year FTE counts are divided by the number of days in the respective cost reporting periods and multiplied by 123:<sup>112</sup>

++ **Prior year:**  $40 \times (123 \div 365) = 13.48$  FTEs.

++ **Penultimate year:**  $39 \times (123 \div 365) = 13.14$  FTEs.

The rolling average therefore equals:  $(13.44 + 13.48 + 13.14) \div 3 = 13.35$  FTEs.

• **Per resident amount:** Hospital A's updated single PRA for its most recently settled cost reporting period ending June 30, 2021, was \$134,000. This PRA must be updated from the calendrical midpoint of Hospital A's June 30, 2021 fiscal year to the midpoint of the period 07/01/23–10/31/23, that is, from December 30, 2020, to August 31, 2023, using an appropriate inflation factor to estimate the change in the CPI-U during this period. Accordingly, Hospital A's FY 2021 PRA is updated by an inflation factor of 1.1777:  $\$134,000 \times 1.1777 =$

<sup>111</sup> From the providers' most recently settled cost reports, as explained below under Notes.

<sup>112</sup> This assumes that Hospital A's prior- and penultimate-year CRPs are both standard 12-month periods.

\$157,812. (The calculation of the inflation factor itself is omitted for the sake of brevity.)

- *Medicare patient load:* Based on the data from the table noted previously, Hospital A's Medicare Part A patient load for the period 07/01/23–10/31/23 is  $8,303 \div 18,450 = 0.45$ ; the Medicare Advantage patient load for the same period is  $2,768 \div 18,450 = 0.15$ .

With these data points established, we can calculate total Part A and MA DGME payment for Hospital A during the pre-merger period 07/01/23–10/31/23. (Note: MA DGME payment is reduced by the percentage determined by CMS for calendar year 2023 and published in the **Federal Register**):

- *Part A:*  $\$157,812 \times 13.35 \times 0.45 = \$948,055.59$ .
- *MA:*  $\$157,812 \times 13.35 \times 0.15 \times (1 - 0.0274) = \$307,359.62$ .

Thus, Hospital A's total DGME payment for the pre-merger period is:  $\$948,055.59 + \$307,359.62 = \$1,255,415.21$ .

#### Post-Merger Direct GME Payment (November 1, 2023, to June 30, 2024)

For the post-merger period, the same payment variables are calculated using data from the records of both the surviving and terminating providers:

- *FTE resident count:* The combined weighted DGME resident count of Hospitals A and B (that is, the newly merged entity) for the period 11/01/23–06/30/24 is  $27.72 + 13.20 = 40.92$  FTEs.

- *FTE resident limit:* The merged provider's combined DGME FTE cap is  $40 + 25 = 65$  FTEs, which must be prorated for the partial cost reporting period. Since there are 243 days during the period 11/01/23–06/30/24 and the full cost reporting period includes February 29, the prorated FTE cap equals:  $65 \times (243 \div 366) = 43.16$ , which is greater than the actual weighted DGME count of 40.92. Accordingly, the provider's effective DGME resident count for the post-merger period is 40.92 FTEs.

- *Rolling average FTE count:* To determine a representative three-year rolling average for the post-merger timeframe, we must treat Hospitals A and B as though they had been merged during their preceding two cost reporting periods. Accordingly, the prior-year FTE count used in the rolling average calculation (before proration) is equal to the combined prior-year FTE counts of the two hospitals:  $40 + 21.5 = 61.50$  FTEs; and the penultimate-year FTE count is equal to:  $39 + 19.25 = 58.25$  FTEs. These totals are then divided by the number of days in the

respective cost reporting periods and multiplied by 243:<sup>113</sup>

- *Prior year:*  $61.50 \times (243 \div 365) = 40.94$  FTEs.

- *Penultimate year:*  $58.25 \times (243 \div 365) = 38.78$  FTEs.

The rolling average therefore equals:  $(40.92 + 40.94 + 38.78) \div 3 = 40.21$  FTEs.

- Hospital A's FY 2021 PRA of \$134,000 is updated by an inflation factor of 1.1416 to \$152,974.

- Hospital B's FY 2020 PRA of \$127,500 is updated by an inflation factor of 1.1530 to \$147,007.

To determine the weighted average merged PRA, each hospital's individual PRA is weighted by the number of DGME FTE residents on its most recently settled cost report. Assume that on their FY 2021 and FY 2020 cost reports, Hospitals A and B reported 40 FTEs and 20 FTEs, respectively. The merged PRA is then equal to:  $((40 \times \$152,974) + (20 \times \$147,007)) \div 60 = \$150,985$ .

Finally, the merged PRA as established previously is updated from the calendrical midpoint of Hospital A's June 30, 2023 fiscal year to the midpoint of the period 11/01/23–06/30/24, that is, from December 30, 2022, to March 1, 2024. Using the same methodology as previously, the merged PRA of \$150,985 is updated by an inflation factor of 1.0448 to \$157,749.

- *Medicare patient load:* The Medicare patient load for the period 11/01/23–06/30/24 is determined based on the combined inpatient days attributable to the merged hospitals. Since the period straddles multiple calendar years, separate MA patient loads must be determined for the periods before and after January 1:

- *Part A:*  $29,887 \div 74,720 = 0.399$ .
- *MA (before Jan. 1):*  $3,325 \div 74,720 = 0.044$ .
- *MA (from Jan. 1):*  $9,565 \div 74,720 = 0.128$ .

(In these calculations, the denominator is equal to the total number of inpatient days at the merged hospital for the entire period 11/01/23–06/30/24 (that is, the sum of the inpatient days at Hospitals A and B, as indicated in the table noted previously); the numerators are obtained by summing the relevant categories of inpatient days for the respective periods.)

With these data points established, we can calculate total Part A and MA

DGME payment for the merged provider during the post-merger period 11/01/23–06/30/24. (Note: MA DGME payments are reduced by the percentages determined by CMS for calendar years 2023 and 2024 and published in the **Federal Register**):

- *Part A:*  $\$157,749 \times 40.21 \times 0.399 = \$2,530,891.83$ .
- *MA (before Jan. 1):*  $\$157,749 \times 40.21 \times 0.044 \times (1 - 0.0274) = \$271,448.61$ .
- *MA (from Jan. 1):*  $\$157,749 \times 40.21 \times 0.128 \times (1 - 0.0233) = \$792,997.55$

Thus, the provider's total DGME payment for the post-merger period is:  $\$2,530,891.83 + \$271,448.61 + \$792,997.55 = \$3,595,337.99$ .

#### Subsequent Cost Reporting Periods (FYEs June 30, 2025, and June 30, 2026)

Direct GME payments for subsequent cost reporting periods are based on the provider's merged DGME payment rates and calculated according to the usual procedures. However, during the first two cost reporting periods following the merger (that is, FYE 06/30/25 and FYE 06/30/26), the rolling average must be calculated as though the hospitals had been merged for the entirety of their prior- and penultimate-year cost reporting periods. This ensures that the rolling average is representative of the training that occurs at the post-merger entity. (Note that this procedure applies whether the merger occurs in the middle of the surviving provider's cost reporting period, as in this example, or coincides with the start of a new cost reporting period.)

Accordingly, in this example, the prior- and penultimate-year FTE counts for the merged provider's cost reporting period ending June 30, 2025, would be determined as follows:

- *Prior year:* The prior cost reporting periods of Hospitals A and B are those ending on June 30, 2024, and October 31, 2023, respectively, and the prior-year FTE count is equal to the hospitals' combined weighted FTE counts, determined based on data from the respective cost reports, consistent with the instructions to lines 12 and 13 of Worksheet E–4. (Note that Hospital B's FYE 10/31/23 is its short terminating cost reporting period that began January 1, 2023.) Based on data from the applicable cost reports, and as shown in the table, Hospital A's individual FTE count (subject to the cap) during FYE 06/30/24 is 40 FTEs,<sup>114</sup> while Hospital

<sup>113</sup> This assumes that the hospitals' prior- and penultimate-year CRPs are all standard 12-month periods. If not, the appropriate proration factors would need to be applied *prior to* summing the hospitals' respective FTE counts (since the proration factor would be different for each hospital).

<sup>114</sup> I.e., the lesser of its DGME FTE cap of 40 or the actual weighted FTE count during this period, plus any podiatric or dental FTEs (not applicable to this example). Since the actual weighted FTE count is  $14.28 + 27.72 = 42$ , the effective DGME count for the prior year is 40 FTEs. (Note that this

B's individual FTE count (subject to the cap) during FYE 10/31/23 is 16.55 FTEs.<sup>115</sup>

Since Hospital B's prior cost reporting period was only 10 months long, its prior-year FTE count must be inflated to a 12-month equivalent, consistent with the policy clarified in the August 4, 2025 **Federal Register** (90 FR 36917):  $16.55 \div 304 \times 365 = 19.87$  FTEs. Accordingly, the combined prior-year FTE count of the merged entity is:  $40 + 19.87 = 59.87$  FTEs.

- *Penultimate year:* The penultimate cost reporting periods of Hospitals A and B are those ending on June 30, 2023, and December 31, 2022, respectively. Based on data from the applicable cost reports, and as shown in the table, the sum of the providers' individual FTE counts during those respective periods is equal to:  $40 + 21.5 = 61.50$  FTEs.

For the following cost reporting period ending June 30, 2026, the prior year-FTE count would be the merged provider's weighted DGME count, subject to the cap, as reported on the preceding cost report (FYE 06/30/2025; not shown); and the penultimate-year FTE count would be the hospitals' combined count as determined previously for the periods 07/01/23–06/30/24 and 01/01/23–10/31/23, that is, 59.87 FTEs. Beginning with the provider's FYE 06/30/2027 cost report, the rolling average would be calculated in accordance with normal procedure.

#### b. Calculating IME Payments Following a Merger of Hospitals

As stated previously, when a hospital merger involves one or more teaching hospitals, the surviving provider experiences an influx of FTE residents from the terminating providers' residency programs and absorbs those hospitals' existing IME FTE caps and available beds, resulting in a change to its intern- and resident-to-bed (IRB) ratio. The merged provider also experiences an increase in both Part A and simulated managed care DRG revenue.

prior year-FTE count would be equal to the placeholder value reported on line 11 of Worksheet E–4 of Hospital A's FYE 06/30/2024 cost report.)

<sup>115</sup> On Hospital B's FYE 10/31/23 cost report, the weighted FTE count of 16.55 on Worksheet E–4, line 8, represents 10 months of aggregate rotations allowable for purposes of DGME payment (9.75 during 01/01/23–06/30/23 and 6.80 during 07/01/23–10/31/23, as shown in the table). Hospital B's DGME FTE cap of 25 FTEs, as reported on line 5, would also be prorated to reflect the short cost reporting period:  $25 \div 365 \times 304 = 20.82$ . Thus, Hospital B's prior year DGME FTE count is the lesser of 16.55 FTEs or its prorated DGME FTE cap of 20.82. (Note that this would be equal to the value reported on line 11 of Worksheet E–4 of Hospital B's FYE 10/31/23 cost report.)

The IME payment associated with a particular discharge reflects the payment rates applicable on the date the discharge occurs: if the discharge occurs prior to the effective date of the merger, the provider's individual IME payment rates are used; if the discharge occurs on or after the effective date of the merger, the IME adjustment is computed based on the combined payment rates of the merged providers. For cost reporting purposes, the surviving provider's total IME payment is based on the payment rate(s) applicable during each cost reporting period or portion thereof. Specifically, if the surviving hospital begins a new cost reporting period effective with the date of the merger, then total IME payment for that initial merged period and subsequent periods is determined based on the hospital's new, combined IME payment rates (with special consideration for the IRB ratio cap and rolling average during the first two cost reporting periods, as discussed further later in this section). However, if the merger takes place in the middle of the surviving hospital's cost reporting period, then the hospital's total IME payment for that period must reflect the different payment rates that apply before and after the merger.

Principles similar to what is discussed previously for direct GME apply to the calculation of the surviving provider's total IME payment amounts: that is, the MAC divides the cost reporting period into pre- and post-merger portions and calculates separate IME payments for each portion (according to the procedure described later in this section). In effect, the pre- and post-merger timeframes are treated as though they were individual short cost reporting periods, with virtual payment rates established for each period on the basis of the best available data for all providers and consistent with the FTE counting policies for non-12-month cost reporting periods as clarified in the August 4, 2025 **Federal Register** (90 FR 36915).

To facilitate the calculation of the IME payment amounts, the MAC determines separate intern- and resident-to-bed ratios for the pre- and post-merger portions of the cost reporting period, which involves determining separate FTE resident counts, FTE caps, rolling average FTE counts, and available bed counts, as well as separate application of the IRB ratio cap. The resulting teaching adjustment factors are multiplied by DRG revenue to obtain total Part A and managed care IME payments for the respective timeframes. Specific procedures for determining these variables are discussed later in this section; as clarified previously for

DGME, the pre-merger IME payment rates are based on data from the surviving provider only, while post-merger rates utilize data from all participating hospitals.

#### IRB Ratio—Numerator

The numerator of the current year IRB ratio (prior to the application of the IRB ratio cap) consists of the allowable IME FTE resident count, subject to the IME FTE cap and the three-year rolling average. These variables are determined for the pre- and post-merger periods as follows:

- *FTE resident count—Calculate separately for the pre-merger and post-merger periods:* To determine the partial year IME FTE counts, the sum of allowable rotations for all residents during the pre- and post-merger periods is divided by the actual number of days in each respective period, using data from the master rotation schedule or a similar source (see 90 FR 36915–16 for further details). For the *pre-merger* period, the count includes rotations allowable to the surviving provider only; for the *post-merger* period, the count includes the sum of all rotations allowable to the merged entity.<sup>116</sup>

- *FTE resident limit (cap)—Calculate separately for the pre-merger and post-merger periods:* Consistent with the FTE counting policies clarified in the August 4, 2025 **Federal Register** (90 FR 36917), it is not necessary to prorate the IME cap for non-12-month cost reporting periods; the partial year IME FTE resident limits are thus equal to the hospitals' original FTE caps, including any adjustments, without the application of a proration factor. The *pre-merger* limit is equal to the FTE cap of the surviving provider only, whereas the *post-merger* limit consists of the combined caps of all hospitals participating in the merger. The FTE caps are applied to the partial year FTE resident counts according to the usual procedure as described in the August 4, 2025 **Federal Register** (90 FR 36917). If any of the merged hospitals has residents participating in a rural track program or residents counted under section 422, then those counts and caps are also determined and applied separately for the pre- and post-merger periods.

- *Rolling average FTE count—Calculate separately for the pre-merger and post-merger periods:* The current,

<sup>116</sup> If any of the merged hospitals is training displaced residents or residents in the initial years of a new program, those FTE counts would be determined according to the same procedure and the FTEs would be added to the respective rolling averages calculated for the pre- and post-merger periods.

prior- and penultimate-year IME counts, which serve as the inputs to the three-year rolling average, must also be determined separately for the pre- and post-merger timeframes. The current year FTE counts are calculated as explained previously, while the prior- and penultimate-year counts are obtained from lines 13 and 14 of Worksheet E, Part A, of the respective hospitals' cost reports (without the application of proration factors; see 90 FR 36917). The numerator of the rolling average for the *pre-merger* period consists of the FTE counts of the surviving provider only, while the *post-merger* numerator equals the combined FTE counts of the surviving and terminating providers, simulating what the effect of the merger would have been during the prior and penultimate cost reporting periods.

Note that a "virtual" rolling average must also be calculated for the merged provider's first two cost reporting periods beginning on or after the effective date of the merger: that is, the surviving and terminating providers' FTE counts must be combined as though they were merged during the prior and/or penultimate years. This procedure applies whether or not the merger occurred in the middle of the surviving provider's cost reporting period. Standard computation of the rolling average would resume in the third full post-merger cost reporting period.

Also note that the procedures for determining the partial year IME resident counts, caps, and rolling averages closely resemble the corresponding procedures described previously for direct GME, except that the IME variables are not adjusted relative to a standard 12-month cost reporting period, consistent with the policy clarified in the August 4, 2025 **Federal Register**.

#### IRB Ratio—Denominator (Available Beds)

The denominator of the current year IRB ratio (prior to the application of the IRB ratio cap) consists of the number of available beds, determined for the pre- and post-merger periods as follows:

- *Available bed count—Calculate separately for the pre-merger and post-merger periods:* Consistent with the methodology at 42 CFR 412.105(b), the available bed count is equal to the number of available bed days divided by the number of days in the virtual cost reporting period. For the *pre-merger* period, only the surviving provider's available bed days are counted. Thus, the pre-merger bed count is computed by counting the number of available bed days during the pre-merger period for

the surviving provider, and dividing by the number of days in the pre-merger period. For the *post-merger* period, the count includes the available bed days of the surviving and terminating providers, including any non-teaching hospitals participating in the merger.<sup>117</sup> Thus, the post-merger bed count is computed by counting the number of available bed days during the post-merger period for all participating hospitals, and dividing by the number of days in the post-merger period.

#### IRB Ratio Cap

Similar to the rolling average, the IRB ratio cap must be determined and applied separately for the pre- and post-merger timeframes, with the post-merger cap simulating what the effect of the merger would have been during the hospitals' preceding cost reporting periods:

- *Prior year numerator—Calculate separately for the pre-merger and post-merger periods:* The numerator of the IRB ratio cap is derived from the allowable IME FTE counts, subject to the IME FTE cap (but before application of the rolling average), reported on Worksheet E, Part A, line 12 of the respective hospitals' prior year cost reports: the numerator of the pre-merger cap consists of the FTE count of the surviving provider only (that is, the FTE count reported on line 12 of Worksheet E, Part A, of the surviving provider's prior year cost report), while the numerator of the post-merger cap equals the sum of the FTE counts of the surviving and terminating providers (that is, of the sum of the FTE counts reported on line 12 of Worksheet E, Part A, of each participating hospital's prior year cost report). If a hospital reports displaced residents or residents in the initial years of a new program, or if its FTE count has increased in the current year as a result of an affiliation agreement, then those residents are added to the prior year numerator, consistent with the instructions to line 20 of Worksheet E, Part A.

- *Prior year denominator—Calculate separately for the pre-merger and post-merger periods:* Similarly, the denominator of the IRB ratio cap is derived from the available bed counts reported on Worksheet E, Part A, line 4 of the respective hospitals' prior year cost reports: the denominator of the pre-

merger cap includes the available beds of the surviving provider only, while the denominator of the post-merger cap, consists of the sum of the available beds of the surviving and terminating providers. The available bed counts are obtained from line 4 of Worksheet E, Part A, of the hospitals' prior year cost reports; if any non-teaching hospital participates in the merger, that hospital's bed count would be determined by dividing the prior year Worksheet S–3, Part I, column 3, line 14, plus line 32, by the number of days in the prior year cost reporting period.

For reasons analogous to those discussed elsewhere in this preamble and in the August 4, 2025 **Federal Register** (90 FR 36915), the components of the IRB ratio cap are derived without the application of a proration factor. Consistent with the usual policy under § 412.105(a)(1), the respective IRB ratios and IRB ratio caps, as determined previously, are compared, and the lesser values are used to calculate the teaching adjustment factors for the pre- and post-merger timeframes.

Similar to the rolling average, a "virtual" IRB ratio cap, consisting of the combined FTE and available bed counts of the surviving and terminating providers, must also be determined for the first cost reporting period beginning on or after the effective date of the merger, to simulate what the effect of the merger would have been during the prior year. This procedure applies whether or not the merger occurred in the middle of the surviving provider's cost reporting period. Standard computation of the IRB ratio cap would resume in the second full post-merger cost reporting period.

#### DRG Revenue and Total IME Payment

To calculate total IME payments, the pre- and post-merger teaching adjustment factors, as determined previously, are multiplied by the hospitals' Part A and simulated managed care DRG revenue for the respective timeframes:

- *DRG revenue (Part A and simulated managed care)—Calculate separately for the pre-merger and post-merger periods:* The teaching adjustment factor for the *pre-merger* period is multiplied by the pre-merger DRG revenue of the surviving provider only, while the teaching adjustment factor for the *post-merger* period is multiplied by the combined DRG revenue of the surviving and terminating providers. Both Part A and simulated managed care DRG revenue are accumulated on the Provider Statistical and Reimbursement (PS&R) Report based on claims submitted by the hospital.

<sup>117</sup> Available bed days of terminating non-teaching providers are included in the post-merger count because the IRB ratio represents teaching intensity across the entire merged entity. This is analogous to the inclusion of the inpatient days of non-teaching providers in the Medicare patient load for purposes of determining post-merger DGME payments.

Note that if the surviving and/or terminating providers count additional residents under the provisions of section 422, the total IME payments for those residents would be calculated separately for the pre- and post-merger periods, as applicable, using the special formula multiplier of 0.66.

Since the cost report does not support the use of multiple IME payment rates for portions of a single cost year, the calculations described in this section must be performed off the cost report, and the results are summed to determine total IME payment for the cost reporting period. Placeholder values based on the combined payment rates of the merged hospitals are reported as necessary on the applicable lines of Worksheet E, Part A.<sup>118</sup>

The following example illustrates the application of the policies described previously.

**Example:**

(Note: This example generally replicates the scenario outline previously in the discussion of direct GME payment, adjusted as necessary to reflect the variables involved in the IME payment calculation.)

Consider a merger between teaching Hospitals A and B, effective November 1, 2023, where Hospital A is the surviving provider. Prior to the merger, Hospitals A and B had fiscal year ends of June 30 and December 31, respectively. As the surviving provider, Hospital A elects to maintain its existing fiscal year, and files a cost report for the period July 1, 2023, to June 30, 2024. Since different payment rates apply to the timeframes 07/01/23–10/31/23 and 11/01/23–06/30/24, two separate IME

payment totals must be calculated for Hospital A's cost reporting period ending June 30, 2024. These calculations are performed off the cost report, and the total Part A and managed care payments are reported on lines 29 and 29.01, respectively, of Worksheet E, Part A of the hospital cost report (Form CMS–2552–10). (Hospital B would file a terminating cost report for the period January 1, 2023–October 31, 2023, with IME payment determined in accordance with the rules applicable to short cost reporting periods, as clarified in the August 4, 2025 **Federal Register**.)

The following table summarizes the data that will be used to calculate Hospital A's pre- and post-merger IME payments, based on the surviving and terminating providers' historical cost reports, as well as other sources such as rotation schedules and PS&R reports:

| Data Point                                                | Hospital A   | Hospital B   | Source                                     |
|-----------------------------------------------------------|--------------|--------------|--------------------------------------------|
| IME FTE resident count: 7/1/23 – 6/30/23                  | [not shown]  | 20.00        | Rotation schedule or similar documentation |
| IME FTE resident count: 7/1/23 – 10/31/23                 | 42.00        | 20.00        | Rotation schedule or similar documentation |
| IME FTE resident count: 11/1/23 – 6/30/24                 | 42.00        | 20.00        | Rotation schedule or similar documentation |
| Prior year IME FTE resident count                         | 40.00        | 21.50        | Cost report data                           |
| Penultimate year IME FTE resident count                   | 39.00        | 19.25        | Cost report data                           |
| IME FTE resident limit (including applicable adjustments) | 40.00        | 25.00        | Cost report data                           |
| Available bed count: 7/1/23 – 6/30/23                     | [not shown]  | 250          | Hospital census data                       |
| Available bed count: 7/1/23 – 10/31/23                    | 300          | 250          | Hospital census data                       |
| Available bed count: 11/1/23 – 6/30/24                    | 300          | 250          | Hospital census data                       |
| Prior year available bed count                            | 300          | 250          | Cost report data                           |
| Part A DRG revenue: 7/1/23 – 10/31/23                     | \$15,625,000 | [not shown]  | PS&R report type 110                       |
| Part A DRG revenue: 11/1/23 – 6/30/24                     | \$30,625,000 | \$25,375,000 | PS&R report type 110                       |
| Managed care DRG revenue (simulated): 7/1/23 – 10/31/23   | \$5,187,500  | [not shown]  | PS&R report type 118                       |
| Managed care DRG revenue (simulated): 11/1/23 – 6/30/24   | \$10,125,000 | \$13,750,000 | PS&R report type 118                       |

**Notes:**

- Since the hospitals are merged effective November 1, 2023, Hospital B technically does not have a separate FTE resident count, separate available bed count, or separate DRG revenue during the period 11/01/23–06/30/24; post-merger data for Hospital B are broken out for illustrative purposes only. In addition, Hospital B's pre-merger FTE counts and available bed counts for its 2023 cost year are printed in brackets since they do not factor into the merged provider's IME payment rates for FYE 06/30/24. (However, note that Hospital B's pre-merger FTE and bed counts will be used to calculate the rolling average and the IRB ratio cap for the merged provider's subsequent cost reports, as explained further below.) Hospital B would file its terminating cost report and receive IME payment for the period 01/01/23–10/31/23 in accordance with the rules applicable to short cost reporting periods.

- The prior- and penultimate-year FTE counts are required to calculate the

three-year rolling averages for the pre- and post-merger periods. Hospital A's prior- and penultimate-year cost reporting periods are those ending on June 30, 2023, and June 30, 2022, respectively; Hospital B's are those ending on December 31, 2022, and December 31, 2021.

- The hospitals' IME FTE resident limits include any applicable adjustments, such as those for new programs or slots received under various statutory provisions. For purposes of this example, we assume that neither hospital has received additional residency slots under section 422.

- As explained previously, the available bed count is equal to the number of available bed days divided by the number of days in the cost reporting period (or virtual period, as here). For purposes of this example, we assume that each hospital's available bed count remains constant over time.

Pre-Merger IME Payment (July 1, 2023, to October 31, 2023)

To calculate the surviving provider's IME payment for the pre-merger period 07/01/23–10/31/23, the following variables are determined based on Hospital A's individual records for the relevant timeframe:

- **FTE resident count:** As indicated in the table noted previously, Hospital A's IME FTE resident count during the period 07/01/23–10/31/23 is 42.00 FTEs, based on data from Hospital A's rotation schedules or similar documentation and determined according to the methodology clarified in the August 4, 2025 **Federal Register**.

- **FTE resident limit:** Hospital A's IME FTE resident limit is 40.00, which is less than the actual IME count of 42 FTEs during this timeframe. Accordingly, Hospital A's effective IME resident count for the pre-merger period is 40.00 FTEs. (Note that neither the IME FTE count nor the IME FTE cap is prorated for the short virtual cost reporting period.)

<sup>118</sup> For example, the FTE caps and adjustments of the surviving and terminating providers would be

added and reported on the applicable FTE cap lines

as though the providers had been merged for the entire cost reporting period.



- *Rolling average FTE count:* As shown in the table, Hospital A's prior- and penultimate-year IME FTE counts are 40 and 39 FTEs, respectively.

(Again, note that these values are not prorated for the short cost reporting period.) The rolling average therefore equals:  $(40 + 40 + 39) \div 3 = 39.67$  FTEs.

- *IRB ratio:* The unadjusted IRB ratio for the pre-merger period is equal to the rolling average FTE count divided by the count of available beds:  $39.67 \div 300 = 0.132$ .

- *IRB ratio cap:* The IRB ratio cap is equal to the prior year IME FTE count (subject to the cap but before application of the rolling average) divided by the count of available beds:  $40 \div 300 = 0.133$ , which is greater than the actual IRB ratio of 0.132.

Accordingly, Hospital A's effective IRB ratio for the pre-merger period is 0.132.

- *DRG revenue:* Hospital A's total Part A DRG revenue during the pre-merger period is \$15,625,000, and its simulated managed care DRG revenue (based on shadow claims submitted during the same period) is \$5,187,500.

Based on the data noted previously, the IME teaching adjustment factor for Hospital A during the pre-merger period 07/01/23–10/31/23 equals:  $1.35 \times ((1 + 0.132)^{0.405} - 1) = 0.07$ . Accordingly, Hospital A's total IME payment amounts during this period are:

- *Part A IME:*  $0.07 \times \$15,625,000 = \$1,093,750$ .

- *Managed care (MA) IME:*  $0.07 \times \$5,187,500 = \$363,125$ .

Thus, Hospital A's total IME payment for the pre-merger period is:  $\$1,093,750 + \$363,125 = \$1,456,875$ .

Post-Merger IME Payment (November 1, 2023, to June 30, 2024)

For the post-merger period, the same payment variables are calculated using data from the records of both the surviving and terminating providers:

- *FTE resident count:* The combined IME FTE resident count of Hospitals A and B (that is, the newly merged entity) for the period 11/01/23–06/30/24 is  $42 + 20 = 62.00$  FTEs.

- *FTE resident limit:* The merged provider's IME combined IME cap is  $40 + 25 = 65$  FTEs, which is greater than the actual IME count of 62. Accordingly, the provider's effective IME resident count for the post-merger period is 62.00 FTEs.

- *Rolling average FTE count:* To determine a representative three-year rolling average for the post-merger timeframe, we must treat Hospitals A and B as though they had been merged during their preceding two cost reporting periods. Accordingly, the prior-year FTE count used in the rolling

average calculation is equal to the combined prior-year FTE counts of the two hospitals:  $40 + 21.5 = 61.50$  FTEs; and the penultimate-year FTE count is equal to:  $39 + 19.25 = 58.25$  FTEs. The rolling average therefore equals:  $(62 + 61.5 + 58.25) \div 3 = 60.58$  FTEs.

- *IRB ratio:* The unadjusted IRB ratio for the post-merger period is equal to the rolling average FTE count divided by the total count of available beds at both hospitals:  $60.58 \div (300 + 250) = 0.11$ .

- *IRB ratio cap:* The IRB ratio cap is equal to the combined prior year IME FTE count (subject to the combined cap but before application of the rolling average) divided by the total count of available beds:  $(40 + 21.5) \div (300 + 250) = 0.112$ , which is greater than the actual IRB ratio of 0.11. Accordingly, the merged provider's effective IRB ratio for the post-merger period is 0.11.

- *DRG revenue:* The merged provider's total Part A DRG revenue during the post-merger period is  $\$30,625,000 + \$25,375,000 = \$56,000,000$ , and its simulated managed care DRG revenue (based on shadow claims submitted during the same period) is  $\$10,125,000 + \$13,750,000 = \$23,875,000$ .

Based on the data noted previously, the IME teaching adjustment factor for the merged provider during the post-merger period 11/01/23–06/30/24 equals:  $1.35 \times ((1 + 0.11)^{0.405} - 1) = 0.058$ . Accordingly, the provider's total IME payment amounts during this period are:

- *Part A IME:*  $0.058 \times \$56,000,000 = \$3,248,000$ .

- *Managed care (MA) IME:*  $0.058 \times \$23,875,000 = \$1,384,750$ .

Thus, the provider's total IME payment for the post-merger period is:  $\$3,248,000 + \$1,384,750 = \$4,632,750$ .

Subsequent Cost Reporting Periods (FYE June 30, 2025, and June 30, 2026)

Total IME payments for subsequent cost reporting periods are based on the provider's merged IME payment rates and calculated according to the usual procedures. However, during the first cost reporting period following the merger (that is, FYE 06/30/25), the IRB ratio cap must be calculated as though the hospitals had been merged for the entirety of their prior cost reporting periods. In addition, as for direct GME, during the first two cost reporting periods following the merger (that is, FYE 06/30/25 and FYE 06/30/26), the rolling average must be calculated as though the hospitals had been merged for the entirety of their prior- and penultimate-year cost reporting periods. This ensures that both the IRB ratio cap

and the rolling average are representative of the training that occurs at the post-merger entity. (Note that this procedure applies whether the merger occurs in the middle of the surviving provider's cost reporting period, as in this example, or coincides with the start of a new cost reporting period.)

Accordingly, in this example, the IRB ratio cap for the merged provider's cost reporting period ending June 30, 2025, would be determined as follows:

- *Prior-year numerator:* The prior cost reporting periods of Hospitals A and B are those ending on June 30, 2024, and October 31, 2023, respectively, and the prior-year FTE count is equal to the hospitals' combined IME FTE counts, determined based on data from the respective cost reports, consistent with the instructions to line 20 of Worksheet E, Part A. (Note that Hospital B's FYE 10/31/23 is its short terminating cost reporting period that began January 1, 2023.) Based on the data from the applicable cost reports, and as shown in the table, Hospital A's individual FTE count (subject to the cap but before application of the rolling average) during FYE 06/30/24 is 40 FTEs, while Hospital's B's individual FTE count (subject to the cap but before application of the rolling average) during FYE 10/31/23 is 20 FTEs.<sup>119</sup> Accordingly, the combined prior year numerator is equal to  $40 + 20 = 60.00$  FTEs.

- *Prior-year denominator:* As shown in the table, the hospitals' total available bed count during their prior cost reporting periods is equal to  $300 + 250 = 550$  beds.

Thus, the IRB ratio cap for the merged provider during this period is:  $60 \div 550 = 0.11$ . Beginning with the provider's FYE 06/30/2026 cost report, the IRB ratio cap would be calculated in accordance with normal procedure.

For a demonstration of how to calculate the rolling average for the cost reporting periods ending on June 30, 2025, and June 30, 2026, refer to the direct GME example earlier in this preamble. Beginning with the provider's FYE 06/30/2027 cost report, the rolling average would be calculated in accordance with normal procedure.

<sup>119</sup> I.e., the lesser of each hospital's IME FTE cap or actual IME FTE count, plus any podiatric and dental FTEs (not applicable to this example), during the respective periods. In this example, Hospital A's prior year numerator would be equal to the placeholder value reported on line 12 of Worksheet E, Part A, of its FYE 06/30/2024 cost report; while Hospital B's prior year numerator would be equal to the value reported on line 12 of Worksheet E, Part A, of its FYE 10/31/2023 cost report.



## 5. Notice of Closure of Teaching Hospitals and Opportunity To Apply for Available Slots

### a. Background

Section 5506 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, “Affordable Care Act”), authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Section 5506 of the Affordable Care Act instructs the Secretary to establish a process by regulation that redistributes slots from teaching hospitals that close to hospitals that meet certain criteria, with priority given to certain hospitals including those located in the same Core Based Statistical Area (CBSA), in a contiguous CBSA or in the same state as the closed hospital.

Specifically, section 5506 of the Affordable Care Act amended the Act by

adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying language at section 1886(d)(5)(B)(v) of the Act, to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the full-time equivalent (FTE) resident caps in teaching hospitals that closed on or after a date that is 2 years before the date of enactment (that is, March 23, 2008). In the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 72264), we established regulations at 42 CFR 413.79(o) and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from the hospital that closed. We made certain additional modifications to § 413.79 in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply both to teaching

hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that close after August 3, 2010 (75 FR 72215).

### b. Notice of Closure of Delaware County Memorial Hospital Located in Drexel Hill, PA, and the Application Process—Round 27

CMS has learned of the closure of Delaware County Memorial Hospital, located in Drexel Hill, PA (CCN 390081). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round (“Round 27”) of the application and selection process. This round will be the 27th round (“Round 27”) of the application and selection process. The table in this section of this rule contains the identifying information and IME and direct GME FTE resident caps for the closed teaching hospital, which are part of the Round 27 application process under section 5506 of the Affordable Care Act.

**TABLE V.F-01: DELAWARE COUNTY MEMORIAL HOSPITAL FTE RESIDENT CAPS**

| CCN    | Provider Name                     | City and State  | CBSA Code | Terminating Date | IME FTE Resident Cap | Direct GME FTE Resident Cap (including +/- MMA Sec. 422 <sup>1</sup> adjustments) |
|--------|-----------------------------------|-----------------|-----------|------------------|----------------------|-----------------------------------------------------------------------------------|
| 390081 | Delaware County Memorial Hospital | Drexel Hill, PA | 37964     | November 7, 2022 | 28.60 <sup>2</sup>   | 28.73 – 0.77 sec. 422 reduction = 27.96 <sup>3</sup>                              |

<sup>1</sup> Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.

<sup>2</sup> Delaware County Memorial Hospital’s 1996 IME FTE resident cap is 28.60.

<sup>3</sup> Delaware County Memorial Hospital’s 1996 DGME FTE resident cap is 28.73. Under section 422 of the MMA, the hospital received a reduction of 0.77 to its DGME FTE cap: 28.73 – 0.77 = 27.96.

### c. Notice of Closure of Crozer-Chester Medical Center Located in Chester, PA, and the Application Process—Round 28

CMS has learned of the closure of Crozer-Chester Medical Center, located in Chester, PA (CCN 390180).

Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round (“Round 28”) of the application and selection process. This round will be the 28th round (“Round 28”) of the application and selection process. The

table in this section of this rule contains the identifying information and IME and direct GME FTE resident caps for the closed teaching hospital, which are part of the Round 28 application process under section 5506 of the Affordable Care Act.

**TABLE V.F-02: CROZER-CHESTER MEDICAL CENTER FTE RESIDENT CAPS**

| CCN    | Provider Name                 | City and State | CBSA Code | Terminating Date | IME FTE Resident Cap (including ACA Section 5506 <sup>2</sup> adjustments) | Direct GME FTE Resident Cap (including +/- MMA Sec. 422 <sup>1</sup> and ACA Section 5506 <sup>2</sup> adjustments) |
|--------|-------------------------------|----------------|-----------|------------------|----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| 390180 | Crozer-Chester Medical Center | Chester, PA    | 37964     | June 21, 2025    | 88.33 + 12.99 sec. 5506 increase = 101.32 <sup>3</sup>                     | 92.82 – 1.02 sec. 422 reduction + 9.09 sec. 5506 increase = 100.89 <sup>4</sup>                                     |

<sup>1</sup> Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.

<sup>2</sup> Section 5506 of the Affordable Care Act of 2010, Public Law 111–148 and Public Law 111–152, redistributes IME and direct GME residency slots from teaching hospitals that close on or after March 23, 2008.

<sup>3</sup> Crozer-Chester Medical Center’s 1996 IME FTE resident cap is 88.33. Under section 5506 of the ACA, the hospital received an increase of 12.99 to its IME FTE resident cap: 88.33 + 12.99 = 101.32.

<sup>4</sup> Crozer-Chester Medical Center’s 1996 DGME FTE resident cap is 92.82. Under section 422 of the MMA, the hospital received a reduction of 1.02 to its DGME FTE cap and under section 5506 of the ACA, the hospital received an increase of 9.09 to its DGME FTE cap: 92.82 – 1.02 + 9.09 = 100.89.

### d. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days

following notice to the public of a hospital closure (77 FR 53436). Therefore, hospitals that wish to apply for and receive slots from the previously noted hospitals’ FTE resident caps must

submit applications using the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), with application submissions for Round

27 and 28 due no later than [insert date 90 days from date of filing for public inspection]. The Section 5506 application can be accessed at: <https://mearis.cms.gov/public/home>.

CMS will only accept Round 27 and 28 applications submitted via MEARIS™. Applications submitted through any other method will not be considered. Within MEARIS™, we have built in several resources to support applicants:

- Please refer to the “Resources” section for guidance regarding the application submission process at: <https://mearis.cms.gov/public/resources>.
- Technical support is available under “Useful Links” at the bottom of the MEARIS™ web page.
- Application related questions can be submitted to CMS using the form available under “Contact” at: <https://mearis.cms.gov/public/resources>.

Application submission through MEARIS™ will not only help CMS track applications and streamline the review process, but it will also create efficiencies for applicants when compared to a paper submission process.

We have not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received by the application deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Direct Graduate Medical Education (DGME) website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/direct-graduate-medical-education-dgme>. Hospitals should access this website for a list of additional section 5506 guidelines for the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

#### *G. Reasonable Cost Payment for Nursing and Allied Health Education Programs (§ 413.85 and § 413.87)*

##### 1. General

Under section 1861(v) of the Act, Medicare has historically paid providers for Medicare’s share of the costs that providers incur in connection with approved educational activities. The costs of these activities are excluded from the definition of “inpatient hospital operating costs” and are not included in the calculation of payment rates for hospitals or hospital units paid

under the IPPS, IRF PPS, or IPF PPS, and are excluded from the rate-of-increase ceiling for certain facilities not paid on a PPS. These costs are separately identified and “passed through” (that is, paid separately on a reasonable cost basis).

Under the existing regulations at 42 CFR 413.85, approved nursing and allied health (NAH) education programs must meet State licensure requirements or be accredited by a recognized national professional organization. Additionally, an approved NAH education program must be operated by a provider. The most recent substantive rulemakings on these regulations were in the January 12, 2001, final rule (66 FR 3358 through 3374), and in the August 1, 2003, final rule (68 FR 45423 and 45434).

##### 2. Medicare Advantage Nursing and Allied Health Education Payments

Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 (codified at section 1886(l) of the Act) provides for additional payments to hospitals for costs of nursing and allied health education associated with services to Medicare+Choice (now MA) enrollees. Hospitals that operate approved nursing or allied health education programs and receive Medicare reasonable cost reimbursement for these programs may receive additional payments to account for MA enrollees. Section 541 of the BBRA limits total spending under the provision for MA enrollees to no more than \$60 million in any calendar year (CY). (In this document, we refer to the total amount of \$60 million or less as the payment “pool”. We also note that section 4143 of Pub. L. 117–328 waived the \$60 million limit for calendar years 2010 through 2019; see the August 28, 2023 **Federal Register** at 88 FR 59058.) Section 541 of the BBRA also provides that direct graduate medical education (GME) payments for Medicare+Choice (now MA) utilization be reduced to the extent that these additional payments are made for nursing and allied health education programs. The provisions of section 541 are effective for portions of cost reporting periods occurring in a calendar year, on or after January 1, 2000.

Section 512 of the Benefits Improvement and Protection Act (BIPA) of 2000 changed the formula for determining the additional amounts to

be paid to hospitals for Medicare+Choice (now MA) nursing and allied health costs. Under section 541 of the BBRA, the additional payment amount was determined based on the proportion of each individual hospital’s nursing and allied health education payment to total nursing and allied health education payments made to all hospitals. However, this formula did not account for a hospital’s specific Medicare+Choice (now MA) utilization. Section 512 of the BIPA revised this payment formula to specifically account for each hospital’s Medicare+Choice (now MA) utilization. This provision was effective for portions of cost reporting periods occurring in a calendar year, beginning with CY 2001.

The regulations at 42 CFR 413.87 implement these statutory provisions. We first implemented the BBRA NAH Medicare+Choice (now MA) provision in the August 1, 2000, IPPS interim final rule with comment period (IFC) (65 FR 47036 through 47039), and subsequently implemented the BIPA provision in the August 1, 2001 IPPS final rule (66 FR 39909 and 39910). In those rules, we outlined the qualifying conditions for a hospital to receive the NAH Medicare+Choice (now MA) payment, how we would calculate the NAH Medicare+Choice (now MA) payment pool, and how a qualifying hospital would calculate its “share” of payment from that pool. Determining a hospital’s NAH MA payment essentially involves applying a ratio of the hospital-specific NAH Part A payments, total inpatient days, and MA inpatient days, to national totals of those same variables, from cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year. The formula is as follows:

$$\frac{(((\text{Hospital NAH pass-through payment} / \text{Hospital Part A Inpatient Days}) * (\text{Hospital MA Inpatient Days})))}{\text{divided by } ((\text{National NAH pass-through payment} / \text{National Part A Inpatient Days}) * (\text{National MA Inpatient Days}))) * \text{Current Year Payment Pool.}}$$

With regard to determining the total national amounts for NAH pass-through payment, Part A inpatient days, and MA inpatient days, we note that section 1886(l) of the Act, as added by section 541 of the BBRA, gives the Secretary the discretion to “estimate” the national components of the formula noted previously. For example, section 1886(l)(2)(A) of the Act states that the Secretary shall estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under section 1886(h)(3)(D) of

<sup>120</sup> The M+C program in Part C of Medicare was renamed the Medicare Advantage (MA) Program under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which was enacted in December 2003.

the Act to total direct GME payments estimated for the same portions of periods under section 1886(h)(3) of the Act.

Accordingly, we stated in the August 1, 2000, IFC (65 FR 47038) that each year, we would determine and publish in a final rule the total amount of nursing and allied health education payments made across all hospitals during the fiscal year 2 years prior to the current calendar year. We would use the best available cost reporting data for the applicable hospitals from the Hospital Cost Report Information System (HCRIS) for cost reporting periods in the fiscal year that is 2 years prior to the current calendar year.

To calculate the pool, in accordance with section 1886(l) of the Act, we stated that we would “estimate” a total amount for each calendar year, not to exceed \$60 million (65 FR 47038). To calculate the proportional reduction to Medicare+Choice (now MA) direct GME payments, we stated that the percentage is estimated by calculating the ratio of the Medicare+Choice nursing and allied health payment “pool” for the current calendar year to the projected total Medicare+Choice direct GME payments made across all hospitals for the current calendar year. We stated that the projections of Medicare+Choice direct GME and Part A direct GME payments are based on the best available cost report data from the HCRIS (for example, for CY 2000, the projections are based on the best available cost report data from FY 1998 HCRIS), and these payment amounts are increased using the increases allowed by section 1886(h) of the Act for these services

(using the percentage applicable for the current calendar year for Medicare+Choice direct GME and the Consumer Price Index (CPI-U) increases for Part A direct GME). We also stated that we would publish the applicable percentage reduction each year in the IPPS proposed and final rules (65 FR 47038).

Thus, in the August 1, 2000, IFC, we described our policy regarding the timing and source of the national data components for the NAH Medicare+Choice (now MA) add-on payment and the percent reduction to the direct GME Medicare+Choice payments, and we stated that we would publish the rates for each calendar year in the IPPS proposed and final rules. While the rates for CY 2000 were published in the August 1, 2000, IFC (see 65 FR 47038 and 47039), the rates for subsequent CYs were only issued through Change Requests (CRs) (CR 2692, CR 11642, CR 12407). After recent issuance of the CY 2019 rates in CR 12407 on August 19, 2021, we reviewed our update procedures, and were reminded that the August 1, 2000, IFC states that we would publish the NAH Medicare+Choice (now MA) rates and direct GME percent reduction every year in the IPPS rules. Accordingly, for CY 2020 and CY 2021, we proposed and finalized the NAH MA add-on rates in the FY 2023 IPPS/LTCH PPS proposed and final rules. We stated that for CYs 2022 and after, we would similarly propose and finalize the respective NAH MA rates and direct GME percent reductions in subsequent IPPS/LTCH PPS rulemakings (see 87 FR 49073, August 10, 2022).

In this FY 2027 IPPS/LTCH PPS proposed rule, we proposed the rates for CY 2025. Consistent with the use of HCRIS data for past calendar years, we are proposing to use data from cost reports ending in FY 2023 HCRIS (the fiscal year that is 2 years prior to CY 2025) to compile these national amounts: NAH pass-through payment, Part A Inpatient Days, MA Inpatient Days.

For this proposed rule, we accessed the FY 2023 HCRIS data from the third quarterly HCRIS update of 2025. However, to calculate the “pool” and the direct GME MA percent reduction, we “project” Part A direct GME payments and MA direct GME payments for the current calendar year, which in this proposed rule is CY 2025, based on the “best available cost report data from the HCRIS” (65 FR 47038). Next, consistent with the method we described previously in the August 1, 2000, IFC, we increase these payment amounts from midpoint to midpoint of the appropriate calendar year using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME, and the Consumer Price Index-Urban (CPI-U) increases for Part A direct GME). For CY 2025, the direct GME projections are based on the third quarterly update of CY 2023 HCRIS, adjusted for the CPI-U and for increasing MA enrollment.

For CY 2025, the proposed national rates and percentages, and their data sources, are set forth in this table. We intend to update these numbers in the FY 2027 final rule based on the latest available cost report data.

| Proposed CY 2025 NAH MA Rates         | Proposed CY 2025 | SOURCE                                         |
|---------------------------------------|------------------|------------------------------------------------|
| NAH Pass-Through                      | \$288,934,483    | Cost reports ending in FY 2023 HCRIS           |
| Part A Inpatient Days                 | 74,710,041       | Cost reports ending in FY 2023 HCRIS           |
| MA Inpatient Days                     | 17,735,281       | Cost reports ending in FY 2023 HCRIS           |
| Part A Direct GME                     | \$3,066,894,317  | CY 2023 HCRIS + CPI-U + MA enrollment          |
| MA Direct GME                         | \$2,575,061,976  | CY 2023 HCRIS + CPI-U + MA enrollment          |
| Pool (not to exceed \$60 million)     | \$60,000,000     | ((MA DGME / Part A DGME) * (NAH Pass-through)) |
| Percent Reduction to MA DGME Payments | 2.33%            | Pool/MA direct GME                             |

### 3. Proposed Requirements To Prohibit Unlawful Discrimination in Approved Nursing and Allied Health Education Programs and Accreditation Standards

Hospitals may receive nursing and allied health education pass-through payments for costs incurred in connection with approved programs. The statute does not explicitly define “approved programs” for purposes of NAH education payments. Instead, section 1886(l)(1) of the Act refers to “approved educational activities for

nurse and allied health professional training”. Under the existing regulations at § 413.85(e), CMS considers an activity to be an “approved nursing and allied health education program” if the program is a planned program of study that is licensed by State law, or if licensing is not required, is accredited by the recognized national professional organization for the particular activity. The regulations note that such national accrediting bodies include, but are not limited to, the Commission on Accreditation of Allied Health

Education Programs, the National League of Nursing Accrediting Commission, the Association for Clinical Pastoral Education Inc., and the American Dietetic Association.

In the CY 2026 OPPS/ASC final rule (90 FR 54024 through 54027), we finalized changes to the definition of “approved medical residency program” and equivalent terms, to state that accrediting organizations may not use accreditation criteria that promote or encourage discrimination on the basis of race, color, national origin, sex, age,

disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. Our intent in finalizing this policy was to ensure that accreditation for approved medical residency programs would be in compliance with applicable laws related to race-based admission policies and to improve the accreditation process. In this proposed rule, we are proposing a similar policy that would apply to approved medical residency programs themselves. For further details on these existing and proposed policies, we refer readers to the CY 2026 OPPS/ASC final rule and to section V.F.2. of this proposed rule, respectively.

We believe that similar concerns related to unlawful and discriminatory accreditation standards and program requirements also apply to approved nursing and allied health education programs. Therefore, we are proposing to require that, in addition to meeting other applicable requirements, individual NAH education programs and NAH accrediting bodies must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. These policies would be effective October 1, 2026, and would be codified under proposed new 42 CFR 413.84, which would be cross-referenced as necessary by the regulations at § 413.85.

Separately, we propose to remove from § 413.85(e) the language specifying individual accrediting organizations of nursing and allied health education programs. In the January 12, 2001 **Federal Register** (66 FR 3365 through 3366), we eliminated the list of nursing and allied health specialty programs and respective accrediting bodies at § 413.85(e) and instead established the general requirement that an approved NAH program must be a planned program of study that is licensed by State law, or if licensing is not required, is accredited by the recognized national professional organization for the particular activity. Nevertheless, we continued to provide examples of recognized accrediting bodies in the regulations text, specifically, the Commission on Accreditation of Allied Health Education Programs, the National League of Nursing Accrediting

Commission, the Association for Clinical Pastoral Education Inc., and the American Dietetic Association. While it is our understanding that these organizations continue to accredit programs in their respective specialties, we no longer believe it is useful to reference a limited number of specific accreditors in the regulations, given the evolving nature of the field and the large number of additional accrediting bodies active across various disciplines.

#### 4. Proposed Changes to the Regulations for Determining the Net Cost of Nursing and Allied Health Education Programs and Clarifications Regarding the Correct Allocation of Overhead Costs

##### a. Overview of Existing Regulations and Cost Report Instructions

In the January 12, 2001, final rule (66 FR 3358) “Medicare Program; Payment for Nursing and Allied Health Education”, we codified the payment regulations regarding NAH education program costs at 42 CFR 413.85. With regard to determining the net costs that are allowed for “pass-through” payment, § 413.85(d)(2)(i) states that the net cost of approved educational activities is determined by deducting the revenues that a provider receives from tuition and student fees from the provider’s total allowable educational costs that are directly related to approved educational activities. Section 413.85(d)(2)(ii) further states that a provider’s total allowable educational costs are those costs incurred by the provider for trainee stipends, compensation of teachers, and other costs of the activities as determined under the Medicare cost-finding principles in § 413.24. These costs do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support. Worksheet A of the Medicare cost report captures the direct costs associated with a hospital’s various cost centers, including its NAH education programs. The direct costs associated with operating a hospital’s approved NAH education programs are reported on Worksheet A, line 20 (nursing programs) and line 23 (paramedical/allied health education programs). The instructions to these lines state—

*Lines 20 and 23*—If you have an approved nursing or allied health education program that meets the criteria of 42 CFR 413.85(e), classroom and clinical portions of the costs may be allowable as pass-through costs as

defined in 42 CFR 413.85(d)(2). (CMS Pub. 15–2, section 4013.)

In addition to direct costs, hospitals also incur indirect or overhead costs associated with their operations. Overhead costs are assigned to the general service cost centers on lines 1 through 23 of Worksheet A, which are a hospital’s non-patient care/non-revenue producing cost centers, and which include the administrative & general (A&G) cost center on line 5. The general cost report instructions for Worksheet A state—

*Lines 1 through 23*—These lines are for the general service cost centers. These costs are expenses incurred in operating the facility as a whole *that are not directly associated with furnishing patient care* such as, but not limited to mortgage, rent, plant operations, administrative salaries, utilities, telephone charges, computer hardware and software costs, etc. General service cost centers provide services to both general service areas and to other cost centers in the provider. (CMS Pub. 15–2, section 4013; emphasis added.)

Because the costs of operating a hospital’s NAH education programs are not directly associated with furnishing patient care, these cost centers are also included among the general service cost centers on Worksheet A. As noted in the cost report instructions cited previously, general service cost centers may furnish services to other general service areas. Thus, for example, a hospital’s Administrative and General cost center may furnish services to its Nursing and Allied Health Education cost centers.

The regulations and cost report instructions require that, prior to allocating overhead costs to the revenue producing cost centers, a provider must make appropriate reclassifications and adjustments to its direct costs. Worksheet A–6 is used to reclassify costs between cost centers on the cost report, while Worksheet A–8 is used to adjust both revenue and non-revenue producing cost centers for (1) expenses to reflect actual expenses incurred; (2) those items which constitute recovery of expenses through sales, charges, fees, etc.; (3) expenses in accordance with the Medicare principles of reimbursement; and (4) those items which are provided for separately in the cost apportionment process. (CMS Pub. 15–2, section 4016.)

Adjustments, including the recovery of expenses through various forms of revenue, occur prior to cost finding, which is the process by which indirect costs (that is, the costs of the general service cost centers) are allocated to other cost centers (both other general service cost centers and revenue producing cost centers). Worksheets B,

Part I, and B–1 have been designed to accommodate the stepdown method of cost finding described at 42 CFR 413.24(d)(1). Certain other cost adjustments, referred to as post-stepdown adjustments, occur after the allocation of indirect and overhead costs and are reported separately on Worksheet B–2.

On November 17, 2017, CMS issued Transmittal 12, which contained clarifications to the hospital cost report instructions at CMS–2552–10, Pub. 15–2, chapter 40. Transmittal 12 added the following clarification to line 19 of Worksheet A–8:

*Line 19*—For each NAHE program on Worksheet A, line 20, and its subscripts, and Worksheet A, line 23, and its subscripts, enter the revenue adjustments (for tuition, fees, books, etc.) to be applied against total allowable costs that are directly related to the approved NAHE activities. Subscript this line to separately report the revenue offset for each NAHE program reported on line 20 and line 23 [and their subscripts]. (CMS Pub. 15–2, section 4016.)

Transmittal 12 also added to Worksheet B–2 specific instructions for post-stepdown adjustments for certain costs associated with NAHE nonprovider-operated programs under 42 CFR 413.85(g)(2), with the following note:

**Note:** Do not use this worksheet to reduce the total allowable costs that are directly related to the NAHE programs by the revenue received from tuition and student fees. Use Worksheet A–8 to offset NAHE program costs by tuition and student fees (42 CFR 413.85(d)(2)(i)). Do not use a post step-down adjustment. (CMS Pub. 15–2, section 4022.)

In issuing these cost report clarifications in Transmittal 12, CMS was clarifying the rules regarding the appropriate order of operations for assigning costs and allocating overhead to the NAH education pass-through cost centers. Specifically, Transmittal 12 made it clear that adjustments to the direct costs of NAH education programs as a result of revenue received from tuition, student fees and other sources should occur on Worksheet A–8, prior to the allocation of overhead costs, and not as post-stepdown adjustments on Worksheet B–2.

#### b. Recent Litigation and Rulemaking Activity

On February 9, 2024, the U.S. District Court for the District of Columbia (DC) issued a decision involving five plaintiff hospitals (*Mercy Health–St. Vincent Medical Center LLC d/b/a Mercy St. Vincent Medical Center v. Becerra*, 717 F. Supp. 3d 33 (D.D.C. 2024)). The

providers disputed the order of operations for determining “net costs” of approved educational activities under 42 CFR 413.85(d)(2)(i). The providers disagreed with the clarified instructions in Transmittal 12, and argued that the offsets for revenue from tuition and student fees should be made after indirect costs are allocated, using Worksheet B–2, which follows the allocation of indirect costs on Worksheet B, Part I. According to the providers, the regulations require that indirect costs be included as part of a provider’s total allowable educational costs before tuition and student fees are offset, and the clarification of the cost reporting instructions in 2017 was a change in policy that conflicts with the regulations. The court sided with the providers, holding that the plain text of 42 CFR 413.85(d)(2)(i) is consistent with the providers’ interpretation of the order of operations.

In the FY 2026 IPPS proposed rule (90 FR 18280 through 18282), we proposed to revise 42 CFR 413.85(d)(2)(i) to define the net cost of approved educational activities in a manner consistent with the cost reporting clarifications in Transmittal 12. Specifically, we proposed that revenues from tuition, student fees and other sources should be subtracted from the allowable direct costs of a provider’s NAH education programs prior to the allocation of overhead costs. We also clarified that, in order to mitigate the reduction in overhead costs that might result from this procedure, a provider could seek permission from its MAC to utilize a statistical basis other than accumulated cost for the purpose of allocating indirect costs to its nursing and allied health cost centers. More specifically, we explained that a provider may elect to subscript its administrative and general cost center (line 5 of Worksheet A) for overhead costs directly related to its NAH programs and employ a statistical basis other than accumulated cost that would accurately reflect the services rendered to those departments. In addition, we stated that the proposed order of operations to offset revenue from direct costs on Worksheet A–8 would be consistent with the policy that A&G costs allocated to the NAH cost centers must be *directly related* to the operation of specific approved programs, as finalized in the January 12, 2001 **Federal Register** (66 FR 3367).

We received many comments in opposition to our proposal to determine the net cost of approved nursing and allied health education programs by deducting tuition and other revenue from direct costs prior to the allocation of indirect costs. Commenters objected

that the proposed policy would be inconsistent with general cost-finding principles and would result in the NAH cost centers receiving less than their share of institutional overhead. Due to the number and nature of the comments we received, we decided not to finalize changes to our existing policy in the FY 2026 IPPS final rule (90 FR 36921). Instead, we stated that we expected to revisit the treatment of NAH education costs in future rulemaking.

After considering the feedback we received on our earlier proposal, we continue to believe, for the reasons stated below, that correct accounting procedures require the deduction of tuition and other revenue from the direct costs of a provider’s approved educational activities on Worksheet A–8, prior to the allocation of overhead, consistent with the clarifications contained in Transmittal 12. However, we acknowledge that it would be helpful to provide additional technical context to explain how the proposed order of operations is consistent with general Medicare cost-finding principles. We are also modifying our original proposal to ensure that the deduction of revenue on Worksheet A–8 does not inappropriately reduce the allocation of overhead to the NAH cost centers when hospitals allocate administrative and general costs using accumulated cost as the default statistical basis.

In addition, we recognize that some portions of our discussion in the FY 2026 proposed rule may have caused confusion about our existing policies regarding allowable indirect costs of approved nursing and allied health education programs. In particular, some commenters believed that we had defined allowable indirect costs in such a way as to essentially preclude the recognition of overhead for purposes of NAH pass-through payment. Therefore, in this proposed rule, we are also proposing to clarify the nature of allowable indirect costs of approved educational activities and to refine the cost reporting procedures to ensure that hospitals appropriately allocate overhead costs to the NAH cost centers.

#### c. Determination of Net Cost of Approved Nursing and Allied Health Education Activities (§§ 413.85(d)(2)(i) and (ii))

We are proposing to change the regulations text at 42 CFR 413.85(d)(2)(i) and (ii) to state that the net cost of approved educational activities is determined by taking the allowable direct costs incurred by the provider for trainee stipends and compensation of faculty employed by the provider, and

subtracting from those direct costs the revenues the provider receives from students or on behalf of students enrolled in the program, such as, but not limited to, tuition, student fees, or textbooks purchased for resale. After subtracting revenues from allowable direct costs, indirect costs would be allocated to the nursing and allied health cost centers (limited to those costs that the provider itself incurs in connection with the operation of its approved educational activities), consistent with Medicare cost-finding principles at 42 CFR 413.24. The effective date of this proposed change would be cost reporting periods beginning on or after October 1, 2026. We are not proposing changes to the existing portion of the regulations at § 413.85(d)(2)(ii) stating that net NAH costs do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support. (We discuss our proposed clarification of allowable indirect costs of educational activities and the associated cost reporting procedures in the following subsection of this preamble.)

As we stated in the FY 2026 proposed rule (90 FR 18281), we understand that it is not uncommon for a provider's allowable nursing and allied health education programs to generate revenues from tuition, student fees and other sources that exceed the allowable direct costs the provider incurs for those programs. Because of that, the revenue offset on Worksheet A–8 might result in a zero or negative balance prior to the allocation of overhead costs; on Worksheet B–1, the accumulated cost statistic, which serves as the recommended statistical basis for allocating administrative and general costs, would consequently also be reduced to zero. Even if the provider were to componentize their administrative and general cost center (consistent with the procedures proposed below), certain components might continue to be allocated on the basis of accumulated cost, limiting the amount of A&G allocated to the provider's NAH cost centers, regardless of the extent to which those cost centers benefit from the hospital's administrative functions.

In order to ensure that the deduction of revenue on Worksheet A–8 does not understate the administrative and general costs allocated to the NAH cost centers, we are proposing the following modifications to the procedures for offsetting revenue and computing the

accumulated cost statistic. First, we are proposing that providers offset the total revenue generated by each NAH program, which may result in a credit balance (negative amount) on the corresponding line(s) of Worksheet A. Next, we propose that providers utilize the reconciliation column on Worksheet B–1 to adjust the accumulated cost statistic by the total amount of NAH revenue offset on Worksheet A–8, effectively reversing that offset for purposes of overhead allocation only.

The following example illustrates the application of this procedure in the event that total revenues from tuition and other sources exceed the direct costs that the provider incurs for a particular NAH program. (Note, the same procedure would be followed if total revenues do not exceed direct costs.)

- Suppose that Hospital A incurs \$1,000,000 in direct costs for an allied health education program; Hospital A reports \$1,000,000 on line 23, column 5, of Worksheet A, which represents the direct costs of the program prior to any adjustments.

- Hospital A receives \$1,200,000 in tuition and fees from students enrolled in the program; Hospital A reports a revenue adjustment of \$1,200,000 on line 19, column 2, of Worksheet A–8, representing a recovery of expenses associated with that program.

- The revenue adjustment of \$1,200,000 carries over to line 23, column 6, of Worksheet A. This results in a negative expense of (\$200,000) (\$1,000,000 minus \$1,200,000 equals (\$200,000)) on line 23, column 7. Assume for purposes of this example that there are no further adjustments (positive or negative) to Hospital A's direct NAH costs.

- On Worksheet B–1, the hospital then utilizes the reconciliation column (line 23, column 5A) to increase the accumulated cost statistic by the amount of revenue offset previously, \$1,200,000. (Note: in the cost report software, the provider must ensure to indicate “override with value” and check to add this value to the existing accumulated cost from Worksheet B, Part I, line 23, column 4A.)

- The accumulated cost statistic for purposes of allocating A&G on Worksheet B, Part I, will be equal to the adjusted expense on Worksheet A, column 7, line 23, plus the amount of revenue from tuition and fees deducted on Worksheet A–8, plus any amounts already allocated to the NAH cost center on Worksheet B, Part I, line 23, columns 1 through 4.

- From this point, the stepdown process on Worksheet B, Part I,

continues according to normal procedures. While the accumulated cost statistic will thus allocate an appropriate share of institutional overhead to the NAH cost center, the amount of NAH costs available for allocation on Worksheet B, Part I, line 23, column 23, will continue to reflect the revenue offset, ensuring that the unallowable costs are not allocated from NAH to the patient care cost centers.

We emphasize that the deduction of tuition and other revenue on Worksheet A–8, prior to the allocation of indirect costs on Worksheet B, Part I, is consistent with general Medicare cost-finding principles as described in PRM 15–1, chapter 23, and the cost report instructions in PRM 15–2, chapter 40, and as codified in the regulations at 42 CFR 413.24. The general service cost centers, including the NAH cost centers, represent a hospital's allowable non-patient care expenses, which are allocated to all the cost centers they serve via the stepdown method on Worksheet B, Part I. Once these expenses have been allocated to the patient care cost centers, Medicare's share of allowable costs is determined based on the hospital's Medicare utilization. It is therefore necessary to remove those costs that are not generally allowable to Medicare *prior to* the stepdown process. Such generally unallowable costs include indirect expenses that are recovered through related non-patient care revenue, as reported on lines 6 through 25 on Worksheet G–3 (including tuition on line 19). For example, interest expense and cafeteria expense are allowable general service non-patient care expenses; however, interest expense is reduced by investment income, and cafeteria expense is reduced by income from the sale of food and drink. Similarly, the tuition and other revenue received for a hospital's nursing and allied health education programs constitute non-patient care revenues that must be used to offset (reduce) the related NAH program expense on Worksheet A–8, consistent with the handling of other non-patient care revenue as described above.

We would also like to take the opportunity to address concerns raised in response to the FY 2026 proposed rule that the proposed order of operations for deducting tuition and other revenue would be inconsistent with our treatment of organ acquisition costs, which are also reimbursed on a pass-through basis. In contrast to the NAH cost centers, the organ acquisition cost centers are ancillary/revenue-producing centers related to patient care. Revenue for organs sold to other

organ procurement organizations or transplant hospitals may only be used to reduce Medicare's share of costs for organs claimed as Medicare usable organs. Those costs are not determined until the full apportionment process on Worksheet D-4, after the allocation of indirect costs on Worksheet B, Part I. By contrast, NAH costs are general service (non-revenue-producing) costs that are not directly related to patient care and are reimbursed to the extent the costs incurred have not been recovered through tuition and other fees. Only the net cost that the hospital actually bears is allocated to other departments. Thus, adjustments for tuition and other NAH revenue must occur on Worksheet A-8, which modifies total costs, not Medicare's share of costs. (However, note that if there are generally non-allowable costs included in an organ acquisition cost center, those costs would be removed on Worksheet A-8, prior to determining Medicare's share of costs.)

#### d. Identification of Allowable Indirect (Overhead) Costs of Approved Educational Activities

The FY 2026 proposed rule included a discussion of the types of costs allowable for purposes of pass-through payment under 42 CFR 413.85 (90 FR 18281 through 18282). That discussion referred to our longstanding nursing and allied health payment policies finalized in the January 12, 2001 **Federal Register** (66 FR 3367), in which we clarified the meaning of the term "tuition" and specified that "total costs" include direct and indirect costs incurred by a provider that are directly attributable to the operation of an approved educational activity. We explained in the 2001 final rule that such costs do not include usual patient care costs that would be incurred in the absence of the educational activity, such as the salary costs for nursing supervisors who oversee the floor nurses and student nurses; moreover, these costs do not include costs incurred by a related organization.

In the FY 2026 proposed rule, we observed that a significant portion of the indirect costs that certain hospitals allocate to their nursing and allied health cost centers include costs incurred by a related organization (such as a home office), in violation of the regulation at § 413.85(d)(2)(ii),<sup>121</sup> as

well as administrative and general costs that may be incurred by the hospital but are not directly attributable to the operation of the hospital's NAH education programs. We stated that those A&G costs not directly incurred as a result of operating a hospital's NAH education programs are paid as normal operating costs under the IPPS (or other applicable hospital payment system) rather than on a pass-through basis. As examples of such costs, we listed costs that benefit the hospital as a whole and that would generally be incurred in the absence of a provider's NAH programs, such as Infection Control, Admissions, Patient Registration, Telecommunications, etc. We stated that it is therefore the provider's responsibility to request permission from its MAC to use an allocation method for overhead costs that accurately and appropriately reflects overhead costs incurred by the provider as a direct result of operating its NAH education programs.

We intended this discussion in the FY 2026 proposed rule to serve as a restatement and clarification of various elements of our existing NAH payment policies. Nevertheless, we received several comments objecting to our characterization of the allowable costs of educational activities. In particular, commenters alleged that we had defined allowable indirect costs in such a way as to effectively preclude the allocation of overhead to the NAH cost centers, by requiring that indirect costs be "directly attributable" to the operation of a provider's NAH education programs. One commenter also objected to our examples of unallowable indirect costs and specifically to our characterization of the salary costs of a nursing supervisor as "usual patient care costs that would be incurred in the absence of the educational activity" and that are thus not allowable for purposes of NAH pass-through payment. We are therefore taking this opportunity to further clarify our existing policies concerning the nature of allowable costs of nursing and allied health, as well as to propose specific procedures for correctly allocating those costs on the hospital cost report.

First, we propose to clarify the meaning of the statement in the January 12, 2001, final rule that "total costs" include only "direct and indirect costs incurred by a provider that are directly attributable to the operation of an approved educational activity." We note that these costs are explicitly contrasted with "usual patient care costs that

would be incurred in the absence of the educational activity, such as the salary costs for nursing supervisors who oversee the floor nurses and student nurses" (66 FR 3367). With respect to the assignment of direct costs on Worksheet A, the purpose of this requirement is to distinguish between the costs of NAH educational activities engaged in by the hospital's nursing and allied health staff, which would not occur in the absence of a hospital's approved NAH programs and which are thus "directly attributable" to the operation of such programs, and the costs of usual patient care services, which may be furnished by some of the same staff members and which the hospital would incur even in the absence of its NAH programs.

For example, a nursing supervisor who oversees floor nurses and student nurses may spend part of his or her time engaged in usual patient care activities, such as monitoring patient vital signs or directing the clinical activities of the floor nurses, and part of the time instructing students in the hospital's nursing program. A portion of the salary costs of the nursing supervisor would be considered direct costs of the nursing program, and the salary costs would thus be apportioned between the hospital's patient care and nursing education cost centers, based on the percentage of time the supervisor spent on each activity. This procedure is analogous to the apportionment of the salary costs of teaching physicians who spend part of their time supervising residents and part of their time providing clinical services to the hospital's patients.

With respect to the allocation of indirect costs on Worksheet B, Part I, the requirement that such costs must be "directly attributable to the operation of an approved educational activity" does not categorically preclude the allocation of institutional overhead to the nursing and allied health cost centers. Rather, this requirement emphasizes the general principle that indirect costs allocated to a particular cost center must *proportionately* reflect the extent to which that department benefits from the hospital's various overhead functions. For example, if only certain staff in a hospital department work on administrative functions related to the NAH program, then only the salary costs of those particular staff, and not the costs of the entire department/cost center, should be allocated to the NAH cost centers, as only the salary costs of those particular staff are "directly attributable to the operation of an approved educational activity." We are clarifying that, if a hospital's nursing or

<sup>121</sup> In addition to the regulation under 413.85(d)(2)(ii), we note that under § 413.85(f)(1)(i), the provider itself must directly incur the training costs in order for a program to be deemed provider-operated and thus eligible for pass-through payment. Accordingly, we caution related parties about incurring NAH training costs (including

indirect costs), as that could jeopardize the provider's status as the operator of the program.



allied health education program benefits from a particular overhead function whose costs are incurred directly by the provider (rather than a related party), then the corresponding NAH cost center must only receive a proportional share of the indirect costs associated with that function, since the function may also provide a benefit to the hospital's other departments, and since the provider would have incurred costs for that function in the absence of its approved NAH programs. That is, the fact that hospital departments are complex and service multiple areas of the hospital necessitates a distinction between those costs that do and do not provide a benefit to a hospital's NAH programs, and the accurate apportionment of only those costs that provide a benefit to the NAH cost centers. Furthermore, we reiterate the policy finalized in the January 12, 2001, **Federal Register** that allowable costs do *not* include costs incurred by a related organization, such as a corporate home office.

If a program does *not* derive a benefit from a particular overhead function, then it should *not* receive any of the indirect costs that the provider incurs for that function. In the FY 2026 proposed rule, we listed examples of several types of overhead, such as Infection Control, Admissions, Patient Registration, Telecommunications, etc., that we believe would usually not provide a benefit to hospitals' NAH education programs, and whose costs should therefore not be allocated to the NAH cost centers. However, we recognize that hospitals' operations vary and that different NAH programs may require different forms of administrative support, potentially including one or more of the functions enumerated in the FY 2026 proposed rule. As stated above, whether or not a particular overhead cost should be allocated to the NAH cost centers depends on whether or not that function provides a benefit to the hospital's NAH programs.

The general service cost centers, including the administrative and general cost center, comprise a variety of distinct overhead functions, some of which may benefit the hospital's nursing and allied health education programs, while others may not. In order to properly distinguish between the costs associated with these distinct functions, and to ensure that the pass-through cost centers receive only those indirect costs allowable under our longstanding policies, we are proposing to require providers with approved NAH education programs to componentize (that is, to fragment or subscript) their general service cost

centers according to the procedures described below.

We are proposing that if a hospital operates "approved educational activities," as defined under § 413.85(c) and subject to the provider-operated requirements under § 413.85(f), then the hospital must identify any general service cost center that comprises costs of multiple overhead functions, where some of those functions provide a benefit to the hospital's NAH programs and others do not. For each such general service cost center, the hospital must create one or more subscripts that contain only those costs that provide a benefit to its NAH programs. (Note that such costs may also provide a benefit to other departments of the hospital.) As a result of this process, the general service cost center would contain the following components (in addition to any other subscripts created by the hospital for other purposes): (1) Indirect costs that provide a benefit to the hospital's NAH programs, and (2) Indirect costs that do not provide a benefit to NAH.

Only those costs contained in component (1) would flow to Worksheet D, Parts III and IV, to be reimbursed on a pass-through basis. On lines 20 and 23 (and subscripts thereof) of Worksheet B-1, the hospital would delete (zero out) the allocation statistic in the column corresponding to component (2), so that those costs are allocated to the departments that they serve but not to the NAH cost centers.

We note that a similar procedure would apply to certain nonprovider-operated programs paid for clinical costs on a pass-through basis under 42 CFR 413.85(g)(1) and (2). In contrast to provider-operated programs paid under § 413.85(f), providers that qualify for reasonable cost payment of clinical costs associated with nonprovider operated programs under § 413.85(g) may receive reasonable cost payment for the clinical training costs only, including the clinical training costs incurred by a related organization (§ 413.85(g)(2)(v); 66 FR 3367); however, the January 12, 2001 **Federal Register** explicitly states that "overhead costs incurred by a related organization generally would not be considered allowable" under this provision (66 FR 3369). Accordingly, under our proposal, a provider that claims pass-through costs under §§ 413.85(g)(1) and (2) must further distinguish between overhead costs incurred directly by the provider and those incurred by a related party. This would be accomplished by creating an additional subscript of the general service cost center containing only those

related party costs.<sup>122</sup> We further note that any excess clinical training costs as defined at § 413.85(g)(2)(iii) would continue to be removed as a post-stepdown adjustment on Worksheet B-2, consistent with the instructions in CMS Pub. 15-2, section 4022.

These procedures would ensure that only indirect costs incurred by the provider that are "directly attributable" to the provider's operation of approved educational activities are allocated to the pass-through NAH cost centers. We note that the componentization of general service cost centers is consistent with longstanding Medicare cost reporting procedures as described in CMS Pub. 15-1, chapter 23, section 2307(B). In addition, we are clarifying that the hospital must ensure that the statistical basis used to allocate each general service cost center and its subscripts (if applicable) must reasonably relate to the general service costs and must appropriately reflect the proportion of those costs attributable to the downstream cost centers, including NAH. For further discussion of the use of appropriate allocation statistics, refer to section X.D.3. of this proposed rule ("Clarification and Codification of Cost Allocation Principles").

The following example illustrates the application of our proposed procedures in the case of a hospital with a subset of administrative and general costs allowable for purposes of NAH pass-through payment. Assume the hospital's NAH programs are deemed provider-operated consistent with the requirements at § 413.85(f).

*Example:* Suppose that a hospital reports \$100,000,000 in administrative and general costs, of which \$75,000,000 is attributable to specific overhead functions (such as executive salaries, accounting services, and facility administrative services) that provide a benefit to the hospital's approved NAH education programs, as well as to the rest of the hospital. The remaining \$25,000,000 is attributable to functions (such as legal services and inpatient admissions) that do not provide a benefit to the hospital's NAH programs.

<sup>122</sup> General service costs incurred by a related party are reported on Worksheet A-8-1 of the hospital cost report. Under our proposal, if the hospital reports related party overhead costs associated with an NAH program on Worksheet A-8-1, then it must create an additional subscript for each corresponding general service cost center containing only those related party costs. Overhead costs incurred by a related organization and allocated to the NAH cost centers would be removed as a post-stepdown adjustment on Worksheet B-2; such costs are not paid on a pass-through basis, but instead are allowable as normal operating costs of the hospital, included in the prospective payment rates.



The hospital would subscript its A&G cost center as follows:

- One subscript (for example, line 5.01), would contain the \$75,000,000 in A&G costs that provide a benefit to the hospital's NAH programs.
- Another subscript (for example, line 5.02), would contain the residual \$25,000,000 in A&G costs not attributable to the hospital's NAH programs.
- Cost center 5.01 would be allocated among all cost centers on an appropriate statistical basis (for example, accumulated cost, adjusted so as to reverse the offset of tuition and/or other revenue, as described in the preceding section of this proposal); any costs allocated to the NAH cost centers would flow to Worksheet D, Parts III and IV, and be reimbursed on a pass-through basis.
- The hospital would delete (zero out) the allocation statistic on Worksheet B–1, lines 20 and 23, column 5.02; this would prevent A&G costs unrelated to the hospital's NAH programs from being allocated to the NAH cost centers.

We propose that the effective date of these policies would be cost reporting periods beginning on or after October 1, 2026. We intend to issue revisions to the hospital cost report (Form CMS–2552–10) to implement these policies, if finalized.

#### *H. Payment Adjustment for Certain Immunotherapy Cases (§§ 412.85 and 412.312)*

Effective for FY 2021, we created MSDRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3 (85 FR 58599 through 58600). Effective for FY 2022, we revised MSDRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).

Effective for FY 2021, we modified our relative weight methodology for MSDRG 018 to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, under our finalized policy we do not include claims determined to be clinical trial claims that group to MS–DRG 018 when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MSDRG, with the additional refinements that: (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be

included when calculating the average cost for MS DRG 018 to the extent such claims can be identified in the historical data; and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). The term “expanded access” (sometimes called “compassionate use”) is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when, among other criteria, there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition (21 CFR 312.305).<sup>123</sup>

Effective FY 2021, we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access immunotherapy cases that group to MS–DRG 018 using the same methodology that we used to adjust the case count for purposes of the relative weight calculations (85 FR 58842 through 58844). (As previously noted, effective beginning FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).) Specifically, under our finalized policy we apply a payment adjustment to claims that group to MS–DRG 018 and include ICD–10CM diagnosis code Z00.6, with the modification that when the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment will not be applied in calculating the payment for the case. We also finalized that when there is expanded access use of immunotherapy, the payment adjustment will be applied in calculating the payment for the case. Effective FY 2026, we also finalized the application of the payment adjustment for clinical trial and expanded access use of immunotherapy cases to other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost. This payment adjustment is codified at 42 CFR 412.85 (for operating IPPS payments) and 412.312 (for capital IPPS payments), for claims appropriately containing Z00.6, as described previously, and reflects that the

adjustment is also applied for cases involving expanded access use immunotherapy, and that the payment adjustment only applies to applicable clinical trial cases; that is, the adjustment is not applicable to cases where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product. The regulations at 42 CFR 412.85(c) also specify that the adjustment factor will reflect the average cost for cases assigned to MS–DRG 018 that involve expanded access use of immunotherapy, are part of an applicable clinical trial, or for discharges occurring on or after October 1, 2025, other cases where the immunotherapy product is not purchased in the usual manner, such as provided at no cost, to the average cost for all other cases assigned to MS–DRG 018 (90 FR 36922).

For FY 2027, we are proposing to continue to apply an adjustment to the payment amount for expanded access use of immunotherapy and applicable clinical trial cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, that group to MS–DRG 018, calculated using the same methodology, as modified in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59062), that we are proposing to use to adjust the case count for purposes of the relative weight calculations, including our proposed modifications to that methodology for FY 2027, as described in section II.D. of the preamble of this proposed rule.

As discussed in the FY 2024 IPPS/LTCH PPS final rule, the MedPAR claims data now includes a field that identifies whether or not the claim includes expanded access use of immunotherapy. For the FY 2023 MedPAR data and for subsequent years, this field identifies whether or not the claim includes condition code 90. The MedPAR files now also include information for claims with the payer-only condition code “ZC”, which is used by the IPPS Pricer to identify a case where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product so that the payment adjustment is not applied in calculating the payment for the case (for example, see Change Request 11879, available at <https://www.cms.gov/files/document/r10571cp.pdf>). We refer the readers to section II.D. of this proposed rule for further discussion of our proposed methodology for identifying clinical trial claims and expanded access use

<sup>123</sup> <https://www.fda.gov/news-events/expanded-access/expanded-access-keywords-definitions-and-resources>

claims in MS–DRG 018 and our methodology used to adjust the case count for purposes of the relative weight calculations, as modified in the FY 2024 IPPS/LTCH PPS final rule, and as further modified for FY 2026 to identify other claims for which the immunotherapy product was not purchased in the usual manner, such as obtained at no cost.

Using the same methodology that we are proposing to use to adjust the case count for purposes of the relative weight calculations, we are proposing to calculate the adjustment to the payment amount for expanded access use of immunotherapy, applicable clinical trial cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost as follows:

- Calculate the average cost for cases assigned to MS–DRG 018 that: (a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code “ZC”; (b) contain condition code “90”; or (c) contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS–DRG 018.
- Calculate the average cost for all other cases assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for expanded access use of immunotherapy, applicable clinical trial cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost,

that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

We refer the readers to section II.D. of the preamble of this proposed rule for further discussion of our methodology.

Consistent with our calculation of the proposed adjustor for the relative weight calculations, for this proposed rule we are proposing to calculate this adjustor based on the December 2025 update of the FY 2025 MedPAR file for purposes of establishing the FY 2027 payment amount. Specifically, in accordance with 42 CFR 412.85 (for operating IPPS payments) and 412.312 (for capital IPPS payments), we are proposing to multiply the FY 2027 relative weight for MS–DRG 018 by a proposed adjustor of 0.17 as part of the calculation of the payment for claims determined to be applicable clinical trial claims, expanded access use immunotherapy claims, or other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, that group to MS–DRG 018, which includes CAR T-cell and non-CAR T-cell therapies and other immunotherapies. We are also proposing to update the value of the adjustor based on more recent data for the final rule.

#### *I. Hospital Readmissions Reduction Program*

##### **1. Regulatory Background**

Section 1886(q) of the Act sets forth the requirements of the Hospital Readmissions Reduction Program effective for discharges from applicable

hospitals beginning on or after October 1, 2012. Under the Hospital Readmissions Reduction Program, payments to applicable hospitals must be reduced to account for certain excess readmissions after an initial treatment for specified diagnoses (referred to in section 1886(q)(5)(A) of the Act as “applicable conditions”, certain high-volume or high-expenditure conditions specified by the Secretary). We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a general overview of the Hospital Readmissions Reduction Program. We also refer readers to 42 CFR 412.152 through 412.154 for codified Hospital Readmissions Reduction Program requirements.

#### **2. Hospital Readmissions Reduction Program Measures**

##### **a. Summary of Previously Adopted Measures for the Hospital Readmissions Reduction Program**

Table V.K–01 shows the Hospital Readmissions Reduction Program measure set for the FY 2027 program year and subsequent years, that is, the “applicable conditions” used to calculate excess readmission ratios.<sup>124</sup> Additional resources on the measure technical specifications and methodology for the Hospital Readmissions Reduction Program are available on the CMS QualityNet website (available at: <https://qualitynet.cms.gov/inpatient/measures/readmission/methodology>).

**TABLE V.I.-01. SUMMARY OF PREVIOUSLY FINALIZED AND PROPOSED HOSPITAL 30-DAY, ALL-CAUSE, RISK-STANDARDIZED UNPLANNED READMISSION MEASURES IN THE HOSPITAL READMISSIONS REDUCTION PROGRAM**

| Applicable Condition or Procedure                                      | FY 2027 | FY 2028 | FY 2029 |
|------------------------------------------------------------------------|---------|---------|---------|
| Acute Myocardial Infarction                                            | X       | X       | X       |
| Chronic Obstructive Pulmonary Disease                                  | X       | X       | X       |
| Heart Failure                                                          | X       | X       | X       |
| Pneumonia                                                              | X       | X       | X       |
| Coronary Artery Bypass Graft Surgery                                   | X       | X       | X       |
| Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty | X       | X       | X       |
| Sepsis*                                                                |         |         | X*      |

\*In section V.I.2.b. of the preamble of this proposed rule, we are proposing to adopt the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization Measure Beginning with the FY 2029 program year.

<sup>124</sup> § 412.152.

b. Proposed Adoption of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization Measure

(1) Background

Sepsis, or septicemia, is a life-threatening condition that results from the body's dysregulated response to infection and is a leading cause of mortality, hospitalization, and readmission in the United States.<sup>125</sup> It is the most frequent principal diagnosis among non-maternal, non-neonatal inpatients, with over 2.2 million hospitalizations reported in 2018.<sup>126</sup> Of the 1.7 million adults diagnosed with sepsis annually, approximately 20 percent die.<sup>127 128 129</sup>

Consistent with section 1886(q)(5)(A) of the Act, which, as noted above, defines an "applicable condition" in the Hospital Readmissions Reduction Program, sepsis readmissions are both high volume and high expenditure. Thirty-day average readmission rates for patients with sepsis are estimated to be about 21 percent.<sup>130</sup> Sepsis is also associated with poor health outcomes, such as the development of chronic conditions and functional impairment,<sup>131</sup> as well as higher costs compared to other conditions included in CMS value-based and quality reporting programs.<sup>132</sup> Between 2016

and 2021, the aggregate hospital costs for patients with sepsis aged 65 and older increased from \$16.7 billion to \$26.3 billion, and the average total cost of sepsis stays for this population increased from \$21,700 to \$25,000 over this period.<sup>133</sup> Approximately 50 percent of the total hospital costs for sepsis stays in 2020 and 2021 were associated with stays expected to be billed to Medicare.<sup>134</sup> A recent study concluded that the quality reporting and payment-for-performance programs should address these concerns after finding that sepsis readmissions occurred at a rate similar to that of other conditions included in the Hospital Readmissions Reduction Program (for example, heart failure, chronic obstructive pulmonary disease, acute myocardial infarction).<sup>135</sup>

Sepsis readmissions are often preventable, highlighting the need for targeted interventions to reduce sepsis-related mortality and improve post-discharge outcomes including readmissions.<sup>136</sup> Readmission following a sepsis hospitalization may be a result of inadequate treatment of the initial infection, complications of hospital care, or secondary to the many challenges in implementation of care transitions and immediate post-discharge care among a complex patient population.<sup>137 138</sup> Research has demonstrated that targeted quality improvement initiatives can reduce

sepsis readmission rates. One study at a large, academically-affiliated hospital showed that the use of multimodal interventions, such as clinical decision support tools, sepsis response teams, standardized order sets, and data-driven quality tracking, have been associated with a lower rate of infection-related readmissions as well as lower overall readmission rates.<sup>139</sup> Another study of patients with severe sepsis showed that post-discharge strategies, including timely home health visits and outpatient physician follow-up within the first week, reduced all-cause 30-day readmissions.<sup>140</sup> A randomized clinical trial at a multisite facility showed that a multicomponent post-sepsis transition service led by a nurse navigator was associated with a 20 percent reduced risk of 30-day readmission or mortality compared to usual care.<sup>141</sup> These findings highlight the effectiveness of both in-hospital and post-discharge quality improvement efforts in improving outcomes for sepsis patients.

(2) Overview of Measure

We propose adopting the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure (Sepsis Readmission measure) for the Hospital Readmissions Reduction Program beginning with an applicable period of July 1, 2025, to June 30, 2027, for the FY 2029 program year. The purpose of the Sepsis Readmission measure is to improve patient outcomes by providing patients, physicians, hospitals, and policymakers with important information about hospital-level unplanned readmission rates following hospitalization for sepsis. The Sepsis Readmission measure would encourage hospitals to improve patient safety and the quality of care provided across the care continuum by tracking hospital-level rates of sepsis readmission. The measure would also promote adherence to evidence-based practices, including standardized clinical protocols,

<sup>125</sup> An Assessment of Sepsis in the United States and its Burden on Hospital Care. Rockville, MD: Agency for Healthcare Research and Quality; 2024. AHRQ Pub No. 24-0087.

<sup>126</sup> McDermott K.W., Roemer M. (2021). Most Frequent Principal Diagnoses for Inpatient Stays in U.S. Hospitals, 2018. Healthcare Cost and Utilization Project (HCUP) Statistical Brief #277. Available at: <https://pubmed.ncbi.nlm.nih.gov/34428003/>. Accessed March 23, 2026.

<sup>127</sup> Centers for Disease Control and Prevention. About Sepsis. August 2025. Available at: <https://www.cdc.gov/sepsis/about/index.html>. Accessed March 23, 2026.

<sup>128</sup> U.S. Department of Health and Human Services. Agency for Healthcare Research and Quality. Report to Congress: An Assessment of Sepsis in the United States and its Burden on Hospital Care. 2024. Available at: [https://www.ahrq.gov/sites/default/files/publications2/files/sepsis-report-to-congress\\_0.pdf](https://www.ahrq.gov/sites/default/files/publications2/files/sepsis-report-to-congress_0.pdf).

<sup>129</sup> Page B., Klompas M., Chan C., et al. Surveillance for healthcare-associated infections: hospital-onset adult sepsis events versus current reportable conditions. *Clin Infect Dis* 2021; 73:1013-9.

<sup>130</sup> Shankar-Hari, et al. Rate and Risk Factors for Rehospitalization in Sepsis Survivors: Systematic Review and Meta-analysis. 2020. *Intensive Care Med*; 46(4):619-636. doi: 10.1007/s00134-019-05908-3.

<sup>131</sup> Van der Slikke, E.C., Beumeler, L.F., Holmqvist, M., Linder, A., Mankowski, R.T., & Bouma, H.R. (2023). Understanding post-sepsis syndrome: how can clinicians help?. *Infection and Drug Resistance*, 6493-6511. <https://doi.org/10.2147/IDR.S390947>.

<sup>132</sup> Weiss A., Jiang J. Overview of clinical conditions with frequent and costly hospital readmissions by payer, 2018 #278. *hcup-*

*us.ahrq.gov*. Published 2021. <https://hcup-us.ahrq.gov/reports/statbriefs/sb278-Conditions-Frequent-Readmissions-By-Payer-2018.jsp>.

<sup>133</sup> Owens, P.L., et al. (2024). Overview of Outcomes for Inpatient Stays Involving Sepsis, 2016-2021 (HCUP Statistical Brief No. 306). Agency for Healthcare Research and Quality. Available at: <https://hcup-us.ahrq.gov/reports/statbriefs/sb306-overview-sepsis-2016-2021.pdf>.

<sup>134</sup> Owens, P.L., et al. (2024). Overview of Outcomes for Inpatient Stays Involving Sepsis, 2016-2021 (HCUP Statistical Brief No. 306). Agency for Healthcare Research and Quality. Available at: <https://hcup-us.ahrq.gov/reports/statbriefs/sb306-overview-sepsis-2016-2021.pdf>.

<sup>135</sup> Cam C., Bridging the Gap: Developing a Standardized Metric for Sepsis Readmission Using CMS Methodology. Hospital Quality Institute. 2025. <https://hqinstitute.org/file/analysis-paper-developing-a-standardized-metric-for-sepsis-readmission-using-cms-methodologies/>.

<sup>136</sup> Taylor, Stephanie et al., 43: Effect of a Navigator-Led Transition and Recovery Program on Mortality and Readmission After Sepsis. *Critical Care Medicine* 49(1):p 22. (2021). doi: 10.1097/01.ccm.0000726200.09497.d2.

<sup>137</sup> Ackermann K., Lynch I., Aryal N., Westbrook J., Li L. Hospital readmission after surviving sepsis: A systematic review of readmission reasons and meta-analysis of readmission rates. *Journal of Critical Care*. 2025/02/01/2025;85:154925. doi:<https://doi.org/10.1016/j.jcrc.2024.154925>.

<sup>138</sup> Gadre S.K., Shah M., Mireles-Cabodevila E., Patel B., Duggal A. Epidemiology and Predictors of 30-Day Readmission in Patients With Sepsis. *CHEST*. 2019;155(3):483-490. doi:10.1016/j.chest.2018.12.008.

<sup>139</sup> Alnababteh M.H., Huang S.S., Ryan A., McGowan K.M., Yohannes S.A. Multimodal Sepsis Quality-Improvement Initiative Including 24/7 Screening and a Dedicated Sepsis Response Team-Reduced Readmissions and Mortality. *Crit Care Explor*. 2020 Nov. 24;2(12):e0251. doi: 10.1097/CCE.0000000000000251.

<sup>140</sup> Deb P., Murtaugh C.M., Bowles K.H., et al. Does Early Follow-Up Improve the Outcomes of Sepsis Survivors Discharged to Home Health Care? *Medical Care*. 2019;57(8):633-640. doi:10.1097/mlr.0000000000001152.

<sup>141</sup> Taylor S.P., Murphy S., Rios A., et al. Effect of a Multicomponent Sepsis Transition and Recovery Program on Mortality and Readmissions After Sepsis: The Improving Morbidity During Post-Acute Care Transitions for Sepsis Randomized Clinical Trial\*. *Critical Care Medicine*. 2022. <https://doi.org/10.1097/CCM.0000000000005300>.

implementation of targeted post-discharge interventions, and appropriate discharge planning. This measure would also give consumers meaningful insights into the quality of care received by Medicare patients.<sup>142</sup>

The measure aligns with our Meaningful Measures 2.0 priority area of “Seamless Care Coordination,” which aims to ensure patients receive timely and coordinated care, reduce the risk of errors, and improve overall patient outcomes.<sup>143</sup> The Sepsis Readmission measure has been specified to include both Medicare Fee-for-Service and Medicare Advantage beneficiaries. Including Medicare Advantage beneficiaries in CMS hospital outcome

measures helps ensure that hospital quality is measured consistently across all Medicare beneficiaries.<sup>144</sup> This is also consistent with the program’s finalization of a policy in the FY 2026 IPPS/LTCH PPS final rule to integrate Medicare Advantage beneficiaries into the cohorts of the Hospital Readmissions Reduction Program measure set beginning with the FY 2027 program year (90 FR 36923 through 36929).

The proposed Sepsis Readmission measure addresses a significant performance gap in healthcare quality. Sepsis represents a critical public health challenge, with substantial variation in hospital readmission rates following an index sepsis hospitalization. This variation reflects differences in the quality of initial treatment, discharge planning, and post-discharge care transitions across healthcare facilities.

Based on our calculations using data from 2022 to 2023, the mean 30-day all-cause risk-standardized readmission rate (RSRR) for sepsis using the proposed measure methodology (see section V.I.b.4. of the preamble of this proposed rule for the proposed Sepsis Readmission measure methodology) for all hospitals with at least 25 eligible discharges for the measure is about 18.09 percent. Among hospitals with at least 25 eligible discharges for the Sepsis Readmission measure, hospitals with a Disproportionate Share Hospital (DSH) patient percentage of at least 65 percent and teaching hospitals with 100 or more residents have the highest mean RSRRs (18.63 percent and 18.62 percent, respectively). Additionally, safety-net hospitals with at least 25 eligible discharges have a slightly higher mean RSRR than non-safety-net hospitals with at least 25 eligible discharges (18.37 percent and 18.02 percent, respectively).

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<sup>142</sup> <https://p4qm.org/measures/5275>. Accessed March 23, 2026.

<sup>143</sup> Centers for Medicare & Medicaid Services. (November 2025). Cascade of Meaningful Measures. Available at: <https://www.cms.gov/medicare/quality/cms-national-quality-strategy/meaningful-measures-20-moving-measure-reduction-modernization>. Accessed March 23, 2026.

<sup>144</sup> <https://p4qm.org/measures/5275>. Accessed March 23, 2026.

**TABLE V.I.-02: MEAN SEPSIS RSRRS BY HOSPITAL CHARACTERISTIC**

|                                                                                   | <b>Number of Hospitals<br/>with 25 or more Sepsis<br/>Discharges <sup>[a]</sup></b> | <b>Mean Sepsis Risk<br/>Standardized Readmission<br/>Rate (%) <sup>[b]</sup></b> |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| <b>All Hospitals</b>                                                              | 2,597                                                                               | 18.09                                                                            |
| <b>By Geographic Location</b>                                                     |                                                                                     |                                                                                  |
| <b>Urban hospitals</b>                                                            | 2,037                                                                               | 18.14                                                                            |
| 1-99 beds                                                                         | 376                                                                                 | 17.84                                                                            |
| 100-199 beds                                                                      | 627                                                                                 | 18.16                                                                            |
| 200-299 beds                                                                      | 393                                                                                 | 18.32                                                                            |
| 300-399 beds                                                                      | 270                                                                                 | 18.21                                                                            |
| 400-499 beds                                                                      | 118                                                                                 | 18.02                                                                            |
| 500 or more beds                                                                  | 253                                                                                 | 18.23                                                                            |
| <b>Rural hospitals</b>                                                            | 556                                                                                 | 17.90                                                                            |
| 1-49 beds                                                                         | 209                                                                                 | 17.74                                                                            |
| 50-99 beds                                                                        | 180                                                                                 | 17.93                                                                            |
| 100-149 beds                                                                      | 94                                                                                  | 18.13                                                                            |
| 150-199 beds                                                                      | 42                                                                                  | 17.99                                                                            |
| 200 or more beds                                                                  | 31                                                                                  | 18.05                                                                            |
| <b>By Teaching Status <sup>[c]</sup></b>                                          |                                                                                     |                                                                                  |
| No teaching                                                                       | 1,357                                                                               | 17.97                                                                            |
| Fewer than 100 residents                                                          | 941                                                                                 | 18.09                                                                            |
| 100 or more residents                                                             | 295                                                                                 | 18.62                                                                            |
| <b>By Ownership Type</b>                                                          |                                                                                     |                                                                                  |
| Government                                                                        | 337                                                                                 | 18.05                                                                            |
| Proprietary                                                                       | 501                                                                                 | 18.52                                                                            |
| Voluntary                                                                         | 1,755                                                                               | 17.97                                                                            |
| <b>By Safety-net Status <sup>[d]</sup></b>                                        |                                                                                     |                                                                                  |
| Safety-net hospitals                                                              | 525                                                                                 | 18.37                                                                            |
| Non-safety-net hospitals                                                          | 2,068                                                                               | 18.02                                                                            |
| <b>By Disproportionate Share Hospital (DSH) Patient Percentage <sup>[e]</sup></b> |                                                                                     |                                                                                  |
| 0-24                                                                              | 923                                                                                 | 18.07                                                                            |
| 25-49                                                                             | 1,405                                                                               | 18.01                                                                            |
| 50-64                                                                             | 154                                                                                 | 18.51                                                                            |
| 65 and over                                                                       | 111                                                                                 | 18.63                                                                            |
| <b>By Medicare Cost Report (MCR) Percentage <sup>[f]</sup></b>                    |                                                                                     |                                                                                  |
| 0-24                                                                              | 1,334                                                                               | 18.09                                                                            |
| 25-49                                                                             | 1,223                                                                               | 18.09                                                                            |
| 50-64                                                                             | 35                                                                                  | 18.03                                                                            |
| 65 and over                                                                       | 1                                                                                   | 16.76                                                                            |
| <b>By Region</b>                                                                  |                                                                                     |                                                                                  |
| New England                                                                       | 118                                                                                 | 18.51                                                                            |
| Middle Atlantic                                                                   | 300                                                                                 | 18.32                                                                            |
| East North Central                                                                | 422                                                                                 | 18.15                                                                            |
| West North Central                                                                | 197                                                                                 | 17.75                                                                            |

|                    |     |       |
|--------------------|-----|-------|
| South Atlantic     | 465 | 18.29 |
| East South Central | 216 | 18.02 |
| West South Central | 335 | 18.05 |
| Mountain           | 188 | 17.44 |
| Pacific            | 355 | 18.02 |

**Source:** Proposed measure results based on preliminary Sepsis Readmission measure results that were available using data from January 1, 2022, through December 31, 2023. Preliminary Sepsis Readmission measure results include hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program (such as CAHs) in the estimation of RSRRs. Although data from all subsection (d), Maryland hospitals, and hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program hospitals were used in calculations of each hospital's RSRR, this table does not include results for Maryland hospitals, hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program, and hospitals that are not open as of the October 2025 public reporting open hospital list because these hospitals are not included in the Hospital Readmissions Reduction Program. Data from the FY 2026 IPPS/LTCH PPS proposed rule impact file is used to identify hospital characteristics. The number of hospitals with each characteristic may not sum to the total number of hospitals due to some hospitals having missing characteristic data in the impact file. This table only includes results for hospitals with at least 25 eligible discharges for the sepsis measure, as measure performance cannot be reliably estimated for hospitals with fewer than 25 eligible discharges.

<sup>a</sup> This table only includes results for hospitals with at least 25 eligible discharges for the sepsis measure as measure performance cannot be reliably estimated for hospitals with fewer than 25 eligible discharges.

<sup>b</sup> The RSRR is the ratio of the predicted readmission rate based on the hospital's performance with its patient case mix to the expected readmission rate based on readmission rates at an average hospital with a patient case mix similar to that hospital's, multiplied by the national observed readmission rate.

<sup>c</sup> A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS greater than zero.

<sup>d</sup> A hospital is considered a safety-net hospital if it is in the top DSH quintile.

<sup>e</sup> DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

<sup>f</sup> MCR (Medicare Cost Report) percentage is the percentage of total inpatient stays from Medicare patients.

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As discussed in the Background section, research demonstrates that thirty-day hospital readmissions following sepsis hospitalization often stem from ineffective initial treatment, poor discharge planning, and insufficient post-discharge follow-up. Studies have shown that facilities implementing a higher number of evidence-based transitional care processes experience lower readmission rates, indicating substantial opportunity for quality improvement across the healthcare system.

Given that infection (either new or recurrent) is the leading cause of sepsis-related readmission, and that evidence-based interventions such as care coordination, medication reconciliation, patient education, and timely post-discharge follow-up have been proven effective in reducing readmissions, this measure would provide hospitals with actionable feedback to enhance quality across the entire care continuum and reduce preventable readmissions for a population not captured in CMS' other condition- and procedure-specific readmission measures.

#### (3) Measure Specifications

##### (a) Numerator

The numerator of the measure is defined as Medicare Fee-for-Service or Medicare Advantage beneficiaries aged

65 years and older, who were discharged from the hospital with a principal diagnosis of sepsis (including post-procedural sepsis), who were then readmitted to an acute care hospital for any cause within 30 days. Patients must have been enrolled in Medicare Fee-for-Service or Medicare Advantage during the index admission and for the 12 months prior to the date of admission, discharged alive from a non-federal short-term acute care hospital, and not transferred to another acute care facility. Only an unplanned inpatient admission to a short-term acute care hospital can qualify as a readmission. Planned readmissions, which are generally not a signal of quality of care, are not included in the numerator. For details of the measure methodology, we refer readers to the measure methodology report, available at: <https://qualitynet.cms.gov/inpatient/measures/readmission/methodology>.

##### (b) Denominator

The measure denominator includes all Medicare Fee-for-Service or Medicare Advantage beneficiaries aged 65 years and older, hospitalized at non-federal short-term acute care hospitals who are discharged alive following a principal hospital discharge diagnosis of sepsis (including post-procedural sepsis), and with a continuous 12-

month Medicare enrollment period prior to the index hospitalization.

This measure excludes index admissions for patients who meet additional exclusion criteria, including: (1) admissions during which patients leave the hospital against medical advice (AMA) (excluded because providers may not have the opportunity to deliver full care and prepare the patient for discharge); (2) admissions for patients without at least 30 days post-discharge enrollment in Medicare Fee-for-Service or Medicare Advantage (excluded because the 30-day readmission outcome cannot be assessed in this group); (3) admissions resulting in patients discharged to hospice (readmission may not be a meaningful outcome for these hospice patients and the discharging hospital is not the most appropriate party to hold accountable for the readmission from hospice for this measure); (4) sepsis admissions captured in the pneumonia readmission measure (to avoid overlap with the pneumonia readmission measure); and (5) sepsis admissions within 30 days of an eligible sepsis index admission (excluded because they are considered readmissions, not index admissions). For more information about the measure specifications, we refer readers to the methodology report, available at: <https://qualitynet.cms.gov/>

*inpatient/measures/readmission/methodology.*

#### (c) Risk Adjustment

To account for differences in case mix across hospitals, the Sepsis Readmission measure includes risk adjustments for patient factors such as age, comorbid diseases, and indicators of patient frailty. The measure also adjusts for the aggressiveness of the infectious organism (bacteria, virus, or fungus) causing sepsis, a transplant recipient indicator, and clinical markers of severe sepsis. These factors are included in risk adjustment calculations for the measure because they are clinically relevant and are related to the measure outcome. For each patient, risk adjustment variables are obtained from inpatient, outpatient, and physician Medicare administrative claims data (Medicare Fee-for-Service Part A and Part B claims, hospital-submitted Medicare Advantage claims, and Medicare Advantage Organization-submitted encounter data) extending up to 12 months prior to the index hospitalization, and secondary diagnoses documented as present on admission during the index hospitalization. The risk adjustment does not include complications that arise during the course of the index hospitalization because they reflect the quality of care delivered and fall within the causal pathway rather than patient risk.<sup>145</sup> For more information on risk adjustment we refer readers to the methodology report, available at: <https://qualitynet.cms.gov/inpatient/measures/readmission/methodology>.

#### (4) Calculating Sepsis Risk-Standardized Readmission Rate

The Sepsis Readmission measure calculates hospital-level 30-day all-cause risk-standardized readmission rates (RSRR) for sepsis. If this measure is adopted as proposed, the sepsis RSRR would be calculated as the ratio of the number of predicted readmissions based on the hospital's performance with its observed case mix to the number of expected readmissions based on the average national level of performance with that hospital's case mix, multiplied

by the national observed readmission rate. This is the same measure calculation methodology as the current measures in the Hospital Readmissions Reduction Program. For more detail on how the Sepsis Readmission measure would be used to calculate the 30-day Risk-Standardized Readmission Rate we refer readers to the methodology report available at: <https://qualitynet.cms.gov/inpatient/measures/readmission/methodology>.

#### (5) Calculating the Excess Readmission Ratio

If finalized as proposed, the Sepsis Readmission measure would use the same methodology and statistical modeling approach as the current measures in the Hospital Readmissions Reduction Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673 through 51676), we finalized the excess readmission ratio pursuant to section 1886(q)(4)(C) of the Act. The ratio is calculated using hierarchical logistic regression. The method adjusts for variation across hospitals in how sick their patients are when admitted to the hospital (and therefore, variation in hospital patients' readmission risk) as well as the variation in the number of patients that a hospital treats to reveal differences in quality. The method produces an adjusted actual (or "predicted") number in the numerator and an "expected" number in the denominator. The expected calculation is similar to that for logistic regression—it is the sum of all patients' expected probabilities of readmission, given their risk factors and the risk of readmission at an average hospital with a similar patient case mix. For each hospital, the numerator of the ratio used in the consensus-based entity methodology (actual adjusted readmissions) is calculated by estimating the probability of readmission for each patient at that hospital and summing up over all the hospital's patients to get the actual adjusted number of readmissions for that hospital. The ratio compares the total adjusted actual readmissions at the hospital to the number that would be expected if the hospital's patients were

treated at an average hospital with similar patients. Hospitals with more adjusted actual readmissions than expected readmissions will have a risk-standardized ratio (excess readmission ratio) greater than one.

For additional detail on the methodology of excess readmission ratio calculations, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380 through 53381). We also refer readers to section V.I.2.b.5. of the preamble of this proposed rule for a description of how the Sepsis Readmission measure would be incorporated into the Hospital Readmissions Reduction Program payment adjustment beginning with the FY 2029 program year.

#### (6) Reliability Testing

Reliability testing was conducted to assess the consistency and stability of the Sepsis Readmission measure in distinguishing hospital performance. The testing methodology evaluated whether observed differences in hospital readmission rates reflect true differences in quality of care rather than random variation.

The reliability analysis employed standard statistical approaches to examine measure performance across hospitals with varying patient volumes. Specifically, we assessed split-half reliability, also called split-sample reliability, to test the internal consistency or stability of the measure. Reliability was estimated both at the measure score and accountable-entity levels.

Reliability testing was assessed using two years of data from January 1, 2022, through December 31, 2023. Table V.I.-03 shows split-half reliability result at the measure score level for hospitals with a minimum case of  $\geq 2$  cases and  $\geq 25$  cases (the proposed threshold for public reporting), respectively. The results indicate that the measure is sufficiently reliable for distinguishing between high- and low-performing hospitals, consistent with the minimum standard for reliability set forth by the Partnership for Quality Measurement ( $\geq 0.60$ ).<sup>146</sup>

**TABLE V.I.-03: MEASURE SCORE SPLIT-HALF RELIABILITY (JANUARY 1, 2022 – DECEMBER 31, 2023)**

| Minimum Case Volume | Number of Hospitals (%) | Number of Patients (%) | Split-half Reliability Score |
|---------------------|-------------------------|------------------------|------------------------------|
| $\geq 2$            | 4,287 (100)             | 1,326,427 (100)        | 0.6                          |
| $\geq 25$           | 3,053 (71.2)            | 1,315,690 (99.2)       | 0.6                          |

<sup>145</sup> <https://p4qm.org/measures/5275>.

<sup>146</sup> For more details on reliability guidance, we refer readers to the Reliability Guidance for the Endorsement and Maintenance of Clinical Quality

Measures Document available at: <https://p4qm.org/em/resources>.

Table V.I.-04 shows the accountable entity-level reliability results for hospitals with a minimum case of  $\geq 25$  cases (the proposed threshold for public reporting). Hospitals were categorized

into volume deciles to assess reliability across different facility sizes and patient populations. Using this method, 69 percent of accountable entities met the split-half reliability estimate threshold

of  $\geq 0.60$ . This indicates that the measure is sufficiently reliable for distinguishing between high- and low-performing hospitals.

**TABLE V.I.-04: ACCOUNTABLE ENTITY LEVEL RELIABILITY ESTIMATE  
(JANUARY 1, 2022 – DECEMBER 31, 2023)**

|                                      | Overall   | Min    | Decile 1 | Decile 2 | Decile 3 | Decile 4 | Decile 5 | Decile 6 | Decile 7 | Decile 8 | Decile 9 | Decile 10 | Max    |
|--------------------------------------|-----------|--------|----------|----------|----------|----------|----------|----------|----------|----------|----------|-----------|--------|
| Mean Reliability                     | 0.82      | 0.205  | 0.254    | 0.384    | 0.521    | 0.642    | 0.727    | 0.782    | 0.826    | 0.862    | 0.894    | 0.932     | 0.986  |
| Mean Performance Score               | 18.083    | 18.107 | 17.444   | 17.964   | 17.934   | 18.037   | 18.064   | 18.134   | 18.164   | 18.177   | 18.204   | 18.21     | 20.756 |
| N of Entities                        | 3,053     | 21     | 312      | 296      | 304      | 305      | 306      | 302      | 308      | 305      | 306      | 304       | 1      |
| N of Persons / Encounters / Episodes | 1,215,690 | 525    | 10,421   | 19,064   | 33,027   | 53,526   | 79,639   | 105,855  | 142,821  | 186,672  | 253,932  | 451,811   | 6,706  |

The Sepsis Readmission measure demonstrates acceptable reliability based on the split-half reliability method, both at the measure score level, and at the entity level. The measure's strong reliability, combined with evidence of substantial performance variation, indicates that it will provide hospitals with actionable, consistent feedback to drive improvements in sepsis care transitions and reduce preventable readmissions.

We also conducted additional analyses to examine coding variability as a source of bias in entity level performance scores; and post-discharge mortality within 30 days of discharge to account for competing risk of mortality in readmission risk. The analyses found no correlation between the hospital level use of sepsis code A41.9 (the most widely used code) and readmission or mortality risk. There was also no correlation between post-discharge mortality and readmission risk at the entity (hospital) level. Post-discharge mortality was stable with increasing duration of time since discharge and up to 30 days. Please refer to the measure methodology report on QualityNet for more detailed information on these analyses, available at: <https://qualitynet.cms.gov/inpatient/measures/readmission/methodology>.

#### (7) Pre-Rulemaking Process and Measure Endorsement

#### (a) Recommendation From the Pre-Rulemaking Measure Review (PRMR) Process

We refer readers to the Partnership for Quality Measurement website for details on the PRMR process, including the voting procedures used to reach consensus on measure recommendations.<sup>147 148</sup> The PRMR

Hospital Committee met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available “2025 Measures Under Consideration List,” including the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure (MUC2025–055).<sup>149</sup>

The voting results of the PRMR Hospital Recommendation Group for the proposed Sepsis Readmission measure within the Hospital Readmissions Reduction Program were as follows: 13 (65 percent) of the Recommendation Group members recommended adopting the measure into the Hospital Readmissions Reduction Program; seven (35 percent) of the Recommendation Group members voted not to recommend the measure for adoption.<sup>150</sup> With 65 percent of the votes for recommend, consensus was not reached, but the majority of the Recommendation Group expressed some support for use of the measure in the Hospital Readmission Reduction Program. Recommendation Group members who voted not to recommend adoption of the measure for the Program provided the following rationales: (1) concerns about adopting the Sepsis Readmission measure directly into the Hospital Readmissions Reduction Program; (2) methodological concerns; and (3) the need for greater consistency

in sepsis definitions across measures and payers.

The Recommendation Group expressed concerns about adopting the Sepsis Readmission measure directly into the Hospital Readmissions Reduction Program, given the payment implications and the perception that hospitals may need time to adapt. Several members recommended a staged approach—initial implementation in the Hospital Inpatient Quality Reporting Program for multiple years, followed by later consideration for Hospital Readmissions Reduction Program—so hospitals have adequate time to understand the measure before the measure is tied to payment.

We appreciate these implementation concerns and agree that careful rollout planning is important for any measure proposed for pay-for-performance programs. We agree that hospitals would benefit from understanding their performance on the Sepsis Readmission measure and potential impacts to their payment under the Hospital Readmissions Reduction Program prior to using the measure for payment adjustments. We considered whether to first adopt this measure in the Hospital Inpatient Quality Reporting Program, in order to give hospitals time to become familiar with the measure before adopting it in a penalty program. However, given the significant morbidity and mortality linked to sepsis and the high case volume and cost of hospital readmissions, we are proposing to adopt the measure directly into the Hospital Readmissions Reduction Program, but using a phased approach, in an effort to balance implementation concerns against our intention to address this CMS priority in a timely manner. We are proposing to implement the Sepsis Readmission measure with “early look” reports for FY 2028—discussed further in section V.I.2.b.6. of the preamble of this proposed rule—that would include sepsis readmission rates as well as estimated Hospital Readmissions Reduction Program payment adjustments with the addition

voting option. The threshold to reach consensus on a given measure continues to be a minimum of 75 percent agreement among members. Committee members can provide considerations for CMS to review prior to implementation.

<sup>149</sup> Centers for Medicare & Medicaid Services. (2025). 2025 Measures Under Consideration (MUC) List. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview>. Accessed February 26, 2026.

<sup>150</sup> Battelle. (February 2026). National Consensus Development and Strategic Planning for Health Care Quality Measurement 2025–2026 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>. Accessed February 26, 2026.

<sup>147</sup> Battelle, Partnership for Quality website. Available at: <https://p4qm.org/>. Accessed March 23, 2026.

<sup>148</sup> In 2025, we updated the PRMR voting process such that committee members will vote to either “recommend” or “do not recommend” that a measure be added to the intended CMS program(s), thus, removing the “recommend with conditions”



of the Sepsis Readmissions measure before beginning to use this measure in the FY 2029 payment adjustment. In addition, we would continue to evaluate measure performance characteristics (including hospital-level reliability, stability year-over-year, and subgroup impacts such as rural/low-volume hospitals) as part of routine measure maintenance.<sup>151</sup>

Committee members also raised methodological concerns, including the perceived imprecision of claims-based readmission measures and uncertainty about risk adjustment adequacy, particularly for rural hospitals and hospitals facing documentation constraints (for example, non-employed clinicians, limited resources). We acknowledge the committee's view of the limitations and variability in accuracy of claims-based measures; however, claims-based readmission measures are widely used in CMS programs because they are nationally scalable, consistently available, and minimize provider reporting burden while enabling standardized comparisons across hospitals. For this measure specifically, we conducted analyses to examine variation in the use of sepsis codes across hospitals, stratified by volume of sepsis cases treated, and observed no correlation with 30-readmission or mortality, indicating that documentation practices are not driving hospital measure performance. We wish to emphasize that the risk adjustment variables were identified through a deliberative and empirical process that resulted in a robust risk adjustment model that includes clinically relevant variables such as severity of sepsis, source of infection, how aggressive the infectious organism is, immunocompromised state of the patient, and organ failure/dysfunction. The risk model demonstrated strong calibration and discrimination in testing including for patients with differing severity of sepsis. For more details on our analysis of measure reliability and the risk adjustment methodology, we refer readers to subsection (6) in this section

and to the measure methodology report, available at: <https://qualitynet.cms.gov/inpatient/measures/readmission/methodology>.

Finally, the committee emphasized the need for greater consistency in sepsis definitions across measures and payors, with many urging alignment with Sepsis-3 as the most current international consensus definition.<sup>152</sup> CMS noted that differing definitions can reflect deliberate tradeoffs between sensitivity and specificity;<sup>153</sup> a scan of the literature shows that the most common problems with sepsis diagnoses relates to under-coding by providers.<sup>154</sup> The developer noted that the current approach yields excellent model performance and identifies a clinically meaningful at-risk population for readmission. We appreciate the committee's request for clarity and standardization, particularly given reported coding and claims-denial dynamics that may influence whether sepsis is included on a claim. We note that we conducted analyses to examine coding practices as a factor that impacts performance scores and found no evidence to support this relationship. Further, as a part of routine measure maintenance, we conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences.

#### (b) Measure Endorsement

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The measure was submitted for review in the Fall 2025 cycle. The Cost and Efficiency Recommendation Group reviewed the Hospital-Level, Risk-Standardized 30-day All-Cause Readmission Following Hospitalization for Sepsis (CBE# 5275) on February 6, 2026. The voting results of the Recommendation Group were: 16 members (84 percent) voted to endorse the measure, and 3 members (16

percent) voted not to endorse the measure. With a vote of 84 percent, the measure was endorsed, without conditions.<sup>155</sup>

#### (8) Payment Reductions

The payment adjustment factor under the Hospital Readmissions Reduction Program is calculated as the greater of 1 minus the ratio of aggregate payments for excess readmissions for the applicable condition to aggregate payments for all discharges or the applicable floor adjustment factor, as defined by section 1886(q)(3)(A) of the Act. The definition for "aggregate payments for excess readmissions" is codified at § 412.152 and the methodology to calculate the payment adjustment factor is codified at § 412.154(c).

As a result of the proposal to add sepsis as an applicable condition under the Hospital Readmissions Reduction Program, excess readmissions for sepsis would be included in the calculation of aggregate payments for excess readmissions beginning with the FY 2029 program year. Consistent with the definition codified at § 412.152, aggregate payments for excess readmissions would include the aggregate base operating DRG payments for excess readmissions associated with sepsis, as applicable. Accordingly, the inclusion of sepsis as an applicable condition would be reflected in the calculation of the payment adjustment factor consistent with the established methodology of the program.

To assess the expected impact on hospital payment adjustments resulting from the proposal to adopt the Sepsis Readmission measure, we estimated hospitals' payment adjustment factors including the Sepsis Readmission measure. Table V.I.-05 shows the estimated total Medicare savings with and without the Sepsis Readmission measure included in the program measure set. Based on our analysis, the estimated average payment reduction per penalized hospital when including the Sepsis Readmission measure increased by approximately \$63,500.

<sup>151</sup> We conduct an annual reevaluation of measures implemented in its quality reporting and value-based purchasing programs to ensure that they remain valid and reflective of current clinical practice and coding standards. As part of this process, we may update measure cohorts, risk adjustment models, or outcomes, as appropriate. These updates are informed by review of the most recent scientific literature, stakeholder input, empirical analyses, and assessments of coding trends that may indicate shifts in clinical practice or billing patterns.

<sup>152</sup> Singer M., Deutschman C.S., Seymour C.W., et al. The Third International Consensus Definitions

for Sepsis and Septic Shock (Sepsis-3). *JAMA*. 2016;315(8):801–810. doi:10.1001/jama.2016.0287.

<sup>153</sup> While there is no one consensus definition of sepsis, Sepsis-2 (based mainly on Systemic Inflammatory Response Syndrome criteria or SIRS) is highly sensitive, often identifying patients before severe deterioration. Sepsis-3 (based primarily on Sequential Organ Failure Assessment or SOFA) is highly specific, meaning it risks missing patients. Based on detailed expert clinical and TEP input, we elected to align the measure with Sepsis-2 definition in order to ensure cases were not missed, but also ensured no overlap with existing condition- and procedure-specific 30-day readmission measures.

<sup>154</sup> Liu B., Hadzi-Tosev M., Liu Y., Lucier K.J., Garg A., Li S., Hedde N.M., Rochweg B., Ning S. Accuracy of International Classification of Diseases, 10th Revision Codes for Identifying Sepsis: A Systematic Review and Meta-Analysis. *Crit Care Explor*. 2022 Nov 9;4(11):e0788. doi: 10.1097/CCE.0000000000000788. PMID: 36382338; PMCID: PMC9649267.

<sup>155</sup> Partnership for Quality Measurement. (February 2026). Cost and Efficiency Recommendation Group Fall 2025 Technical Report. Will become available at: <https://p4qm.org/em/news-events>.

**TABLE V.I.-05: ESTIMATED TOTAL MEDICARE SAVINGS OF PROPOSED ADOPTION OF SEPSIS READMISSION MEASURE TO HOSPITAL READMISSIONS REDUCTION PROGRAM MEASURE SET**

|                                  | <b>Current Measure Set<br/>(without sepsis)</b> | <b>Proposed Measure Set<br/>with Sepsis</b> | <b>Difference Between<br/>Proposed and Current<br/>Measure Sets</b> | <b>Percentage Difference<br/>Between Proposed and<br/>Current Measure Sets</b> |
|----------------------------------|-------------------------------------------------|---------------------------------------------|---------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Estimated total Medicare savings | \$361,347,626                                   | \$530,998,964                               | \$169,651,338                                                       | 47%                                                                            |
| Number of penalized hospitals    | 2,358                                           | 2,450                                       | 92                                                                  | 4%                                                                             |

Our analysis, as reflected in Table V.I.-06, also assessed the impact of the proposed Sepsis Readmission measure adoption on the number of hospitals that could be penalized under the Hospital Readmissions Reduction Program (that is, they have 25 or more eligible discharges for at least one measure), the number and percentage of penalized hospitals, and penalties as a share of payments overall and by hospital characteristics. The results for the current measure set are equal to those in Table V.I.-05, which show the estimated results for the FY 2027 Hospital Readmissions Reduction Program by hospital characteristic. The second and sixth columns in Table V.I.-06 indicate the total number of hospitals that could be penalized under the Hospital Readmissions Reduction Program. Poorly performing hospitals included in the program may receive a

penalty if they are non-Maryland subsection (d) hospitals with 25 or more eligible discharges for at least one measure during the applicable period. The third and seventh columns in the table indicate the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals). The fourth and eighth columns in the table indicate the estimated percentage of penalized hospitals among those that could be penalized by hospital characteristic. The fifth and ninth columns in the table estimate the financial impact on hospitals by hospital characteristic, referred to as the penalty as a share of payments. The penalty as a share of payments is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG

payments for those hospitals. For example, under the current measure set without sepsis, the penalty as a share of payments for urban hospitals is 0.48 percent, and with the proposed updates, the penalty as a share of payments for urban hospitals is 0.68 percent. This means that total penalties for all urban hospitals is 0.48 percent of total payments for urban hospitals under the current measure set and 0.68 percent with the proposed measure set to add sepsis. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

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| Hospital Characteristic                                                    | Current Measure Set (without Sepsis Readmission Measure)  |                                              |                                                      | Proposed Measure Set (with Sepsis Readmission Measure) |                                                           |                                              |                                                      |                                                   |
|----------------------------------------------------------------------------|-----------------------------------------------------------|----------------------------------------------|------------------------------------------------------|--------------------------------------------------------|-----------------------------------------------------------|----------------------------------------------|------------------------------------------------------|---------------------------------------------------|
|                                                                            | Number of Hospitals Eligible for a Penalty <sup>(a)</sup> | Number of Penalized Hospitals <sup>(b)</sup> | Percentage of Hospitals Penalized (%) <sup>(c)</sup> | Penalty as a Share of Payments (%) <sup>(d)</sup>      | Number of Hospitals Eligible for a Penalty <sup>(a)</sup> | Number of Penalized Hospitals <sup>(b)</sup> | Percentage of Hospitals Penalized (%) <sup>(c)</sup> | Penalty as a Share of Payments (%) <sup>(d)</sup> |
| All Hospitals                                                              | 2,832                                                     | 2,338                                        | 83.26                                                | 0.48                                                   | 2,836                                                     | 2,458                                        | 86.39                                                | 0.68                                              |
| By Geographic Location                                                     |                                                           |                                              |                                                      |                                                        |                                                           |                                              |                                                      |                                                   |
| Urban hospitals                                                            | 2,180                                                     | 1,876                                        | 86.06                                                | 0.48                                                   | 2,183                                                     | 1,937                                        | 88.73                                                | 0.68                                              |
| 1-99 beds                                                                  | 511                                                       | 358                                          | 70.06                                                | 0.48                                                   | 514                                                       | 382                                          | 74.32                                                | 0.64                                              |
| 100-199 beds                                                               | 635                                                       | 562                                          | 88.50                                                | 0.56                                                   | 635                                                       | 580                                          | 91.34                                                | 0.79                                              |
| 200-299 beds                                                               | 393                                                       | 365                                          | 92.88                                                | 0.57                                                   | 393                                                       | 372                                          | 94.66                                                | 0.84                                              |
| 300-399 beds                                                               | 270                                                       | 251                                          | 92.96                                                | 0.49                                                   | 270                                                       | 256                                          | 94.81                                                | 0.69                                              |
| 400-499 beds                                                               | 118                                                       | 111                                          | 94.07                                                | 0.45                                                   | 118                                                       | 112                                          | 94.92                                                | 0.63                                              |
| 500 or more beds                                                           | 253                                                       | 229                                          | 90.51                                                | 0.39                                                   | 253                                                       | 235                                          | 92.89                                                | 0.57                                              |
| Rural hospitals                                                            | 646                                                       | 480                                          | 74.30                                                | 0.47                                                   | 647                                                       | 509                                          | 78.67                                                | 0.69                                              |
| 1-49 beds                                                                  | 295                                                       | 183                                          | 62.03                                                | 0.37                                                   | 296                                                       | 200                                          | 67.57                                                | 0.47                                              |
| 50-99 beds                                                                 | 184                                                       | 148                                          | 80.43                                                | 0.49                                                   | 184                                                       | 156                                          | 84.78                                                | 0.69                                              |
| 100-149 beds                                                               | 94                                                        | 82                                           | 87.23                                                | 0.52                                                   | 94                                                        | 84                                           | 89.36                                                | 0.84                                              |
| 150-199 beds                                                               | 42                                                        | 38                                           | 90.48                                                | 0.50                                                   | 42                                                        | 39                                           | 92.86                                                | 0.72                                              |
| 200 or more beds                                                           | 31                                                        | 29                                           | 93.55                                                | 0.46                                                   | 31                                                        | 30                                           | 96.77                                                | 0.69                                              |
| By Teaching Status <sup>(e)</sup>                                          |                                                           |                                              |                                                      |                                                        |                                                           |                                              |                                                      |                                                   |
| Non-teaching                                                               | 1,578                                                     | 1,241                                        | 78.64                                                | 0.51                                                   | 1,382                                                     | 1,303                                        | 83.36                                                | 0.72                                              |
| Fewer than 100 residents                                                   | 953                                                       | 838                                          | 87.93                                                | 0.50                                                   | 953                                                       | 859                                          | 90.14                                                | 0.70                                              |
| 100 or more residents                                                      | 295                                                       | 277                                          | 93.90                                                | 0.42                                                   | 295                                                       | 284                                          | 96.27                                                | 0.63                                              |
| By Ownership Type                                                          |                                                           |                                              |                                                      |                                                        |                                                           |                                              |                                                      |                                                   |
| Government                                                                 | 397                                                       | 324                                          | 81.61                                                | 0.32                                                   | 397                                                       | 339                                          | 85.39                                                | 0.47                                              |
| Proprietary                                                                | 611                                                       | 492                                          | 80.52                                                | 0.66                                                   | 612                                                       | 516                                          | 84.31                                                | 0.99                                              |
| Voluntary                                                                  | 1,818                                                     | 1,540                                        | 84.71                                                | 0.47                                                   | 1,821                                                     | 1,591                                        | 87.37                                                | 0.66                                              |
| By Safety-net Status <sup>(f)</sup>                                        |                                                           |                                              |                                                      |                                                        |                                                           |                                              |                                                      |                                                   |
| Safety-net hospitals                                                       | 566                                                       | 470                                          | 83.04                                                | 0.44                                                   | 567                                                       | 498                                          | 87.83                                                | 0.65                                              |
| Non-safety-net hospitals                                                   | 2,260                                                     | 1,886                                        | 83.45                                                | 0.49                                                   | 2,263                                                     | 1,948                                        | 86.08                                                | 0.69                                              |
| By Disproportionate Share Hospital (DSH) Patient Percentage <sup>(g)</sup> |                                                           |                                              |                                                      |                                                        |                                                           |                                              |                                                      |                                                   |
| 0-24                                                                       | 1,069                                                     | 868                                          | 81.20                                                | 0.54                                                   | 1,072                                                     | 899                                          | 83.86                                                | 0.77                                              |
| 25-49                                                                      | 1,470                                                     | 1,235                                        | 83.37                                                | 0.44                                                   | 1,470                                                     | 1,294                                        | 88.03                                                | 0.62                                              |
| 50-64                                                                      | 166                                                       | 132                                          | 79.52                                                | 0.51                                                   | 166                                                       | 144                                          | 86.75                                                | 0.76                                              |
| 65 and over                                                                | 121                                                       | 101                                          | 83.47                                                | 0.58                                                   | 122                                                       | 109                                          | 89.34                                                | 0.89                                              |
| By Medicare Cost Report (MCR) Percentage <sup>(h)</sup>                    |                                                           |                                              |                                                      |                                                        |                                                           |                                              |                                                      |                                                   |
| 0-24                                                                       | 1,404                                                     | 1,192                                        | 84.90                                                | 0.39                                                   | 1,407                                                     | 1,238                                        | 87.99                                                | 0.58                                              |
| 25-49                                                                      | 1,355                                                     | 1,124                                        | 82.95                                                | 0.56                                                   | 1,356                                                     | 1,166                                        | 85.99                                                | 0.79                                              |
| 50-64                                                                      | 60                                                        | 38                                           | 63.33                                                | 0.71                                                   | 60                                                        | 40                                           | 66.67                                                | 0.90                                              |

| Hospital Characteristic | Current Measure Set (without Sepsis Readmission Measure)  |                                              |                                                      | Proposed Measure Set (with Sepsis Readmission Measure)    |                                              |                                                      |
|-------------------------|-----------------------------------------------------------|----------------------------------------------|------------------------------------------------------|-----------------------------------------------------------|----------------------------------------------|------------------------------------------------------|
|                         | Number of Hospitals Eligible for a Penalty <sup>(a)</sup> | Number of Penalized Hospitals <sup>(b)</sup> | Percentage of Hospitals Penalized (%) <sup>(c)</sup> | Number of Hospitals Eligible for a Penalty <sup>(a)</sup> | Number of Penalized Hospitals <sup>(b)</sup> | Percentage of Hospitals Penalized (%) <sup>(c)</sup> |
| 65 and over             | 7                                                         | 2                                            | 28.57                                                | 7                                                         | 2                                            | 28.57                                                |
| <b>By Region</b>        |                                                           |                                              |                                                      |                                                           |                                              |                                                      |
| New England             | 120                                                       | 115                                          | 95.83                                                | 120                                                       | 116                                          | 96.67                                                |
| Middle Atlantic         | 313                                                       | 293                                          | 93.61                                                | 313                                                       | 295                                          | 94.25                                                |
| East North Central      | 443                                                       | 379                                          | 85.55                                                | 443                                                       | 390                                          | 88.04                                                |
| West North Central      | 223                                                       | 176                                          | 78.92                                                | 223                                                       | 185                                          | 82.96                                                |
| South Atlantic          | 483                                                       | 424                                          | 87.42                                                | 486                                                       | 443                                          | 91.15                                                |
| East South Central      | 252                                                       | 208                                          | 82.54                                                | 252                                                       | 219                                          | 86.90                                                |
| West South Central      | 422                                                       | 322                                          | 76.30                                                | 424                                                       | 341                                          | 80.42                                                |
| Mountain                | 206                                                       | 140                                          | 67.96                                                | 207                                                       | 149                                          | 71.98                                                |
| Pacific                 | 367                                                       | 301                                          | 82.02                                                | 367                                                       | 311                                          | 84.74                                                |

Source: Current and proposed measure set results based on preliminary Medicare Advantage and Medicare-Fee-for-Service readmission measure results that were available using data from January 1, 2022, through December 31, 2023. Preliminary Medicare Advantage and Medicare-Fee-for-Service and Sepsis Readmission measure results include hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program (such as CAHs) in the estimation of excess readmission ratios (ERRs). Although data from all subsection (d), Maryland hospitals, and hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program hospitals were used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals. Hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program, and hospitals that are not open as of the October 2025 public reporting open hospital list because these hospitals are not included in the Hospital Readmissions Reduction Program. Dual proportions and Fee-for-Service base operating DRG ratios are calculated from July 1, 2021, through June 30, 2023. MedPAR data from October 1, 2022, through September 30, 2023 (FY 2023) is used to calculate the payment adjustment as a proportion of total base operating DRG payments. Data from the FY 2026 IPPS/LTCH PPS proposed rule impact file is used to identify hospital characteristics. The number of hospitals with each characteristic may not sum to the total number of hospitals due to some hospitals having missing characteristic data in the impact file. This table only includes results for hospitals that could be penalized under the program on the basis of having at least 25 eligible discharges for at least one measure. The average share of penalties as a percentage of all base operating DRG payments is calculated as the sum of all Medicare savings for the group of hospitals divided by total base operating DRG payments for all hospitals in that group.

<sup>a</sup> This column is the number of applicable hospitals within the characteristic that could be penalized (that is, they have 25 or more eligible discharges for at least one measure).

<sup>b</sup> This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

<sup>c</sup> This column is the percentage of applicable hospitals that are penalized among hospitals that could be penalized, by characteristic.

<sup>d</sup> This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments in this way allows for comparisons across hospital characteristics that accounts for differences in the amount of base operating DRG payments for different groups of hospitals. MedPAR data from October 1, 2022, through September 30, 2023 (FY 2023), are used to estimate the total base operating DRG payments.

<sup>e</sup> A hospital is considered a teaching hospital if it has an indirect Medical Education adjustment factor for Operation PPS greater than zero.

<sup>f</sup> A hospital is considered a safety-net hospital if it is in the top DSH quintile.

<sup>g</sup> DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

<sup>h</sup> MCR (Medicare Cost Report) percentage is the percentage of total inpatient stays from Medicare patients.

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## (9) Data Submission, Early Look, and Public Reporting

The Sepsis Readmission measure uses Medicare administrative data (Medicare Fee-for-Service Part A and Part B claims, hospital-submitted Medicare Advantage claims, and Medicare Advantage Organization-submitted encounter data) for Medicare Fee-for-Service and Medicare Advantage beneficiaries hospitalized for sepsis. Because this measure utilizes CMS administrative data, a hospital would not be required to submit additional data for calculating the measure. In the FY 2026 IPPS/LTCH PPS final rule, we finalized our policy to use 2 years of claims data to calculate readmission measures (90 FR 36931 through 36932) in conjunction with the policy to integrate Medicare Advantage beneficiaries into the cohorts of the Hospital Readmissions Reduction Program measure set (90 FR 36923 through 36929) beginning with the FY 2027 program year.

We considered whether to first adopt this measure in the Hospital Inpatient Quality Reporting Program, in order to give hospitals time to become familiar with the measure before adopting it in a penalty program. However, as discussed in section V.I.b.1. of the preamble of this proposed rule, given the significant morbidity and mortality linked to sepsis and the high case volume and cost of hospital readmissions, and our intention to address this CMS priority in a timely manner, we are proposing to adopt the measure in the Hospital Readmissions Reduction Program without delay, but also to provide hospitals with an “early look” of their Sepsis Readmission measure results and estimated Hospital Readmissions Reduction Program payment adjustments with the addition of the Sepsis Readmission measure for the FY 2028 program year, for which the applicable period is from July 1, 2024, to June 30, 2026. Data used in this early look would not be publicly reported or used for payment adjustment; the early look would provide hospitals with confidential reports of their measure and program results prior to public reporting of the Sepsis Readmission measure beginning with the FY 2029 program year.

We are proposing that the Sepsis Readmission measure would be used for payment adjustment beginning with the FY 2029 program year, for which the applicable period is from July 1, 2025, to June 30, 2027. We recognize that the first year of data used to calculate the Sepsis Readmission measure would

include patient data from a period of time predating the proposal of the measure. We note that the approach of including that data in public reporting and payment determination is consistent with prior claims-based measure adoptions in the Hospital Readmissions Reduction Program. We reiterate that this measure would not require any additional data from hospitals and that the proposed implementation timeline would support our goal of addressing the health care quality gap in sepsis care in a timely manner. Consistent with the standard of care for patients with sepsis, we expect that hospitals are already providing the types of discharge planning and care coordination services that would be expected to minimize readmissions. Additionally, more than half of the proposed first reporting period would take place after the intended publication date of the FY 2027 IPPS/LTCH PPS final rule. This would allow hospitals to make any necessary improvements to their discharge planning and care coordination processes. We refer readers to the FY 2015 IPPS/LTCH PPS final rule for an example of such an instance (79 FR 50033 through 50039). If this measure adoption is finalized, we would continue to publicly report readmission rates by publicly posting the readmission measure results annually for the applicable conditions for each hospital on the Compare tool or successor website(s), currently available at <https://www.medicare.gov/care-compare/>, and on the Provider Data Catalog, available at <https://data.cms.gov/provider-data/>, as codified at § 412.154(f).

We invite public comment on our proposal to adopt the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure as part of the Hospital Readmissions Reduction Program measure set beginning with an early look for the FY 2028 program year (applicable period of July 1, 2024, to June 30, 2026), and use for the FY 2029 program year (applicable period of July 1, 2025, to June 30, 2027) and subsequent years.

#### *J. Hospital Value-Based Purchasing Program*

##### *1. Background*

##### *a. Overview*

For background on the Hospital Value-Based Purchasing Program, we refer readers to the CMS website at: <https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-value-based-purchasing>. We also refer readers to our codified

requirements for the Hospital Value-Based Purchasing Program at 42 CFR 412.160 through 412.168.

##### *b. FY 2027 Program Year Payment Details*

Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2027 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2027 is approximately \$1.9 billion, based on the December 2025 update of the FY 2025 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this proposed rule (which is available via the internet on the CMS website). We note that these proxy adjustment factors will not be used to adjust hospital payments. These proxy value-based incentive payment adjustment factors were calculated using the FY 2027 Hospital Value-Based Purchasing Program methodology and historical baseline and performance periods for the FY 2026 Hospital Value-Based Purchasing Program. These proxy factors were calculated using the December 2025 update to the FY 2025 MedPAR file. The slope of the linear exchange function used to calculate these proxy factors was 3.4503276602, and the estimated amount available for value-based incentive payments to hospitals for FY 2027 is approximately \$1.9 billion. We intend to include an update to this table, as Table 16A, with the FY 2027 IPPS/LTCH PPS final rule, to reflect changes based on the March 2026 update to the FY 2025 MedPAR file. We will add Table 16B to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2027 Hospital Value-Based Purchasing Program. We expect that Table 16B will be posted on the CMS website in fall 2026.

##### *2. Hospital Value-Based Purchasing Program Measures*

We are proposing to adopt substantive measure updates to five condition-specific and procedure-specific mortality measures, in the Clinical Outcome domain, beginning with the July 1, 2028 through June 30, 2030

performance period for the FY 2032 program year, which we discuss further in section IX.B.2. of the preamble of this proposed rule. We are proposing these updates contingent on our adopting the same refined mortality measures in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination, which we

discuss further in section IX.B.2. of the preamble of this proposed rule.

a. Summary of Previously Adopted Quality Measures for the Hospital Value-Based Purchasing Program

We refer readers to the FY 2026 IPPS/LTCH PPS final rule for summaries of the previously adopted measures for the

FY 2027 through FY 2031 program years (90 FR 36951). We are not proposing any changes to the measure set. Table V.J.1. summarizes the previously adopted Hospital Value-Based Purchasing Program measure set for the FY 2027 program year.

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**TABLE V.J.1.: SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2027 PROGRAM YEAR**

| Measure Short Name                            | Domain/Measure Name                                                                                                                                                   | CBE #          |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <b>Person and Community Engagement Domain</b> |                                                                                                                                                                       |                |
| HCAHPS*                                       | Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition and Responsiveness of Hospital Staff dimensions)                 | 0166<br>(0228) |
| <b>Safety Domain</b>                          |                                                                                                                                                                       |                |
| CAUTI                                         | National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure                                                         | 0138           |
| CLABSI                                        | National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure                                                      | 0139           |
| Colon and Abdominal Hysterectomy SSI          | American College of Surgeons Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure         | 0753           |
| MRSA Bacteremia                               | National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure | 1716           |
| CDI                                           | National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure                         | 1717           |
| SEP-1                                         | Severe Sepsis and Septic Shock: Management Bundle                                                                                                                     | 0500           |
| <b>Clinical Outcomes Domain</b>               |                                                                                                                                                                       |                |
| MORT-30-AMI                                   | Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization                                              | 0230           |
| MORT-30-HF                                    | Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization                                                             | 0229           |
| MORT-30-PN                                    | Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization                                                                      | 0468           |
| MORT-30-COPD                                  | Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization                                   | 1893           |
| MORT-30-CABG                                  | Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery                                                    | 2558           |
| COMP-HIP-KNEE                                 | Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)                       | 1550           |
| <b>Efficiency and Cost Reduction Domain</b>   |                                                                                                                                                                       |                |
| MSPB                                          | Medicare Spending Per Beneficiary (MSPB) Hospital                                                                                                                     | 2158           |

\*In the FY 2025 IPPS/LTCH PPS final rule, we adopted the updated HCAHPS Survey measure in the Hospital Value-Based Purchasing Program beginning with the FY 2030 program (89 FR 69508 through 69511). The Care Transition and Responsiveness of Hospital Staff dimensions will be included in the HCAHPS Survey but not scored for FY 2027 through FY 2029, and will not be included in the HCAHPS survey beginning with FY 2030.

Table V.J.2. summarizes the previously adopted Hospital Value-Based Purchasing Program measures for

the FY 2028 through FY 2032 program years.

**TABLE V.J.2.: SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2028 THROUGH FY 2032 PROGRAM YEARS**

| Measure Short Name                            | Domain/Measure Name                                                                                                                                                   | CBE #          |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <b>Person and Community Engagement Domain</b> |                                                                                                                                                                       |                |
| HCAHPS*                                       | Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition and Responsiveness of Hospital Staff dimensions)                 | 0166<br>(0228) |
| <b>Safety Domain</b>                          |                                                                                                                                                                       |                |
| CAUTI                                         | National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure                                                         | 0138           |
| CLABSI                                        | National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure                                                      | 0139           |
| Colon and Abdominal Hysterectomy SSI          | American College of Surgeons Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure         | 0753           |
| MRSA Bacteremia                               | National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure | 1716           |
| CDI                                           | National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure                         | 1717           |
| SEP-1                                         | Severe Sepsis and Septic Shock: Management Bundle                                                                                                                     | 0500           |
| <b>Clinical Outcomes Domain</b>               |                                                                                                                                                                       |                |
| MORT-30-AMI**                                 | Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization                                              | 0230           |
| MORT-30-HF**                                  | Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization                                                             | 0229           |
| MORT-30-PN**                                  | Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization                                                                      | 0468           |
| MORT-30-COPD**                                | Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization                                   | 1893           |
| MORT-30-CABG**                                | Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery                                                    | 2558           |
| COMP-HIP-KNEE***                              | Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)                       | 1550           |
| <b>Efficiency and Cost Reduction Domain</b>   |                                                                                                                                                                       |                |
| MSPB                                          | Medicare Spending Per Beneficiary (MSPB) Hospital                                                                                                                     | 2158           |

\* In the FY 2025 IPPS/LTCH PPS final rule, we adopted the updated HCAHPS Survey measure in the Hospital Value-Based Purchasing Program beginning with the FY 2030 program (89 FR 69508 through 69511). The Care Transition and Responsiveness of Hospital Staff dimensions will be included in the HCAHPS Survey but not scored for FY 2027 through FY 2029, and will not be included in the HCAHPS survey beginning with FY 2030.

\*\* In this proposed rule, we propose modifications to the MORT-30-AMI, MORT-30-HF, MORT-30-PN, MORT-30-COPD, MORT-30-CABG measures beginning with the FY 2032 program year. We refer readers to section IX.B.2. of the preamble of this proposed rule for more detailed discussion.

\*\*\* In the FY 2026 IPPS/LTCH PPS final rule, we finalized modifications to the COMP-HIP-KNEE measure in the Hospital Value-Based Purchasing Program beginning with the FY 2033 program year (90 FR 36943 through 36948). The updated COMP-HIP-KNEE measure will include Medicare Advantage beneficiaries in the measure cohort and a reduced reporting period from 3 to 2 years beginning with the FY 2033 program year.

3. Baseline and Performance Periods for the FY 2028 Through FY 2032 Program Years

a. Background

We refer readers to the FY 2026 IPPS/LTCH PPS final rule (90 FR 36951 through 36954) for previously adopted

baseline and performance periods for the FY 2027 through FY 2031 program years. We also refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998) in which we finalized a schedule for all future baseline and performance periods.

b. Summary of Baseline and Performance Periods for the FY 2028 Through FY 2032 Program Years

Tables V.J.3., V.J.4., V.J.5., V.J.6., and V.J.7. summarize the baseline and performance periods that we have previously adopted.

**TABLE V.J.3.: BASELINE AND PERFORMANCE PERIODS FOR THE FY 2028 PROGRAM YEAR**

| Measures                                                                                  | Baseline Period                     | Performance Period                  |
|-------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|
| <b>Person and Community Engagement Domain</b>                                             |                                     |                                     |
| HCAHPS                                                                                    | January 1, 2024 – December 31, 2024 | January 1, 2026 – December 31, 2026 |
| <b>Clinical Outcomes Domain</b>                                                           |                                     |                                     |
| Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN)      | July 1, 2018 – June 30, 2021*       | July 1, 2023 – June 30, 2026        |
| COMP-HIP-KNEE                                                                             | April 1, 2018 – March 31, 2021*     | April 1, 2023 – March 31, 2026      |
| <b>Safety Domain</b>                                                                      |                                     |                                     |
| NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) | January 1, 2024 – December 31, 2024 | January 1, 2026 – December 31, 2026 |
| SEP-1                                                                                     | January 1, 2024 – December 31, 2024 | January 1, 2026 – December 31, 2026 |
| <b>Efficiency and Cost Reduction Domain</b>                                               |                                     |                                     |
| MSPB                                                                                      | January 1, 2024 – December 31, 2024 | January 1, 2026 – December 31, 2026 |

\* These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

**TABLE V.J.4.: BASELINE AND PERFORMANCE PERIODS FOR THE FY 2029 PROGRAM YEAR**

| Measures                                                                                  | Baseline Period                     | Performance Period                  |
|-------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|
| <b>Person and Community Engagement Domain</b>                                             |                                     |                                     |
| HCAHPS                                                                                    | January 1, 2025 – December 31, 2025 | January 1, 2027 – December 31, 2027 |
| <b>Clinical Outcomes Domain</b>                                                           |                                     |                                     |
| Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN)      | July 1, 2019 – June 30, 2022*       | July 1, 2024 – June 30, 2027        |
| COMP-HIP-KNEE                                                                             | April 1, 2019 – March 31, 2022*     | April 1, 2024 – March 31, 2027      |
| <b>Safety Domain</b>                                                                      |                                     |                                     |
| NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) | January 1, 2025 – December 31, 2025 | January 1, 2027 – December 31, 2027 |
| SEP-1                                                                                     | January 1, 2025 – December 31, 2025 | January 1, 2027 – December 31, 2027 |
| <b>Efficiency and Cost Reduction Domain</b>                                               |                                     |                                     |
| MSPB                                                                                      | January 1, 2025 – December 31, 2025 | January 1, 2027 – December 31, 2027 |

\* These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).



**TABLE V.J.5.: BASELINE AND PERFORMANCE PERIODS FOR THE FY 2030 PROGRAM YEAR**

| Measures                                                                                  | Baseline Period                     | Performance Period                  |
|-------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|
| <b>Person and Community Engagement Domain</b>                                             |                                     |                                     |
| HCAHPS                                                                                    | January 1, 2026 – December 31, 2026 | January 1, 2028 – December 31, 2028 |
| <b>Clinical Outcomes Domain</b>                                                           |                                     |                                     |
| Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN)      | July 1, 2020 – June 30, 2023        | July 1, 2025 – June 30, 2028        |
| COMP-HIP-KNEE                                                                             | April 1, 2020 – March 31, 2023*     | April 1, 2025 – March 31, 2028      |
| <b>Safety Domain</b>                                                                      |                                     |                                     |
| NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) | January 1, 2026 – December 31, 2026 | January 1, 2028 – December 31, 2028 |
| SEP-1                                                                                     | January 1, 2026 – December 31, 2026 | January 1, 2028 – December 31, 2028 |
| <b>Efficiency and Cost Reduction Domain</b>                                               |                                     |                                     |
| MSPB                                                                                      | January 1, 2026 – December 31, 2026 | January 1, 2028 – December 31, 2028 |

\* This baseline period is impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculation for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication measure. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

**TABLE V.J.6.: BASELINE AND PERFORMANCE PERIODS FOR THE FY 2031 PROGRAM YEAR**

| Measures                                                                                  | Baseline Period                     | Performance Period                  |
|-------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|
| <b>Person and Community Engagement Domain</b>                                             |                                     |                                     |
| HCAHPS                                                                                    | January 1, 2027 – December 31, 2027 | January 1, 2029 – December 31, 2029 |
| <b>Clinical Outcomes Domain</b>                                                           |                                     |                                     |
| Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN)      | July 1, 2021 – June 30, 2024        | July 1, 2026 – June 30, 2029        |
| COMP-HIP-KNEE                                                                             | April 1, 2021 – March 31, 2024      | April 1, 2026 – March 31, 2029      |
| <b>Safety Domain</b>                                                                      |                                     |                                     |
| NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) | January 1, 2027 – December 31, 2027 | January 1, 2029 – December 31, 2029 |
| SEP-1                                                                                     | January 1, 2027 – December 31, 2027 | January 1, 2029 – December 31, 2029 |
| <b>Efficiency and Cost Reduction Domain</b>                                               |                                     |                                     |
| MSPB                                                                                      | January 1, 2027 – December 31, 2027 | January 1, 2029 – December 31, 2029 |

**TABLE V.J.7.: BASELINE AND PERFORMANCE PERIODS FOR THE FY 2032 PROGRAM YEAR**

| Measures                                                                                  | Baseline Period                     | Performance Period                  |
|-------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|
| <b>Person and Community Engagement Domain</b>                                             |                                     |                                     |
| HCAHPS                                                                                    | January 1, 2028 – December 31, 2028 | January 1, 2030 – December 31, 2030 |
| <b>Clinical Outcomes Domain</b>                                                           |                                     |                                     |
| Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN)      | July 1, 2024 – June 30, 2026*       | July 1, 2028 – June 30, 2030        |
| COMP-HIP-KNEE                                                                             | April 1, 2022 – March 31, 2025      | April 1, 2027 – March 31, 2030      |
| <b>Safety Domain</b>                                                                      |                                     |                                     |
| NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) | January 1, 2028 – December 31, 2028 | January 1, 2030 – December 31, 2030 |
| SEP-1                                                                                     | January 1, 2028 – December 31, 2028 | January 1, 2030 – December 31, 2030 |
| <b>Efficiency and Cost Reduction Domain</b>                                               |                                     |                                     |
| MSPB                                                                                      | January 1, 2028 – December 31, 2028 | January 1, 2030 – December 31, 2030 |

\*In this proposed rule, we propose modifications to the mortality measures beginning with the FY 2032 program year, including a reduced performance period from 3 to 2 years. We refer readers to section IX.B.2. of the preamble of this proposed rule for more detailed discussion.

#### 4. Performance Standards for the Hospital Value-Based Purchasing Program

##### a. Background

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69406 through 69407) for previously established performance standards for the FY 2027 program year. We also refer readers to the FY 2026 IPPS/LTCH PPS final rule (90 FR 36955 through 36957) for the previously established performance standards for the FY 2028 program year.

##### b. Previously Established Performance Standards for Certain Measures for the FY 2029 Through the FY 2031 Program Years

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program

years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36948 through 36950), we made technical updates to the Clinical Outcomes domain beginning with the FY 2027 program year to include COVID-19 patients in the measure data, and thus established new performance standards for the FY 2029 through the FY 2031 program years for the Clinical Outcomes domain measures (MORT-30-AMI, MORT-30-HF, MORT-30-PN, MORT-30-COPD, MORT-30-CABG, and COMP-HIP-KNEE). In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36954 through 36955), we made technical updates to the Safety domain, such that the five National Healthcare Safety Network Healthcare-associated Infection measures (CAUTI, CLABSI, CDI, MRSA Bacteremia, and Colon and

Abdominal Hysterectomy SSI) would use the CY 2022 data to calculate performance standards for the FY 2029 program year and subsequent years. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69409 through 69410), we established performance standards for the FY 2029 through the FY 2030 program years for the Efficiency and Cost Reduction domain measure (MSPB Hospital). We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for Clinical Outcomes domain and the Efficiency and Cost Reduction domain and newly estimated performance standards for the Safety domain measures are set out in Table V.J.8. for the FY 2029 program year.

**TABLE V.J.8.: PREVIOUSLY ESTABLISHED AND NEWLY ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2029 PROGRAM YEAR**

| Measure Short Name                          | Achievement Threshold                                                                              | Benchmark                                                                                                              |
|---------------------------------------------|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>Safety Domain**</b>                      |                                                                                                    |                                                                                                                        |
| CAUTI*                                      | 0.404095                                                                                           | 0                                                                                                                      |
| CLABSI*                                     | 0.473791                                                                                           | 0                                                                                                                      |
| CDI*                                        | 0.277932                                                                                           | 0                                                                                                                      |
| MRSA Bacteremia*                            | 0.597372                                                                                           | 0                                                                                                                      |
| Colon and Abdominal Hysterectomy SSI*       | 0.714669                                                                                           | 0                                                                                                                      |
| SEP-1                                       | 0.810812                                                                                           | 0.873773                                                                                                               |
| <b>Clinical Outcomes Domain♦</b>            |                                                                                                    |                                                                                                                        |
| MORT-30-AMI                                 | 0.873295                                                                                           | 0.891834                                                                                                               |
| MORT-30-HF                                  | 0.87976                                                                                            | 0.906894                                                                                                               |
| MORT-30-PN                                  | 0.801554                                                                                           | 0.842898                                                                                                               |
| MORT-30-COPD                                | 0.905582                                                                                           | 0.924775                                                                                                               |
| MORT-30-CABG                                | 0.970801                                                                                           | 0.979861                                                                                                               |
| COMP-HIP-KNEE*                              | 0.031509                                                                                           | 0.023706                                                                                                               |
| <b>Efficiency and Cost Reduction Domain</b> |                                                                                                    |                                                                                                                        |
| MSPB*                                       | Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period. | Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period. |

\* Lower values represent better performance.

\*\* We note that the numerical values for the performance standards for the HAI and SEP-1 measures in this proposed rule represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2027 IPPS/LTCH PPS final rule. These estimates are based on 10/01/2024–09/30/2025 data.

♦ Previously established performance standards.

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69507 through 69508) where we finalized the policy to modify the scoring of the HCAHPS Survey for the FY 2027 through FY 2029 program years while updates to the survey are publicly reported under the Hospital Inpatient Quality Reporting Program. Scoring is modified to only score hospitals on the six unchanged Hospital Value-Based Purchasing Program dimensions of the HCAHPS Survey until the updates to the HCAHPS Survey have been publicly reported for one year. The six unchanged dimensions of the HCAHPS Survey for the Hospital Value-Based Purchasing Program are as follows:

- “Communication with Nurses,”
- “Communication with Doctors,”
- “Communication about Medicines,”
- “Discharge Information,”
- “Cleanliness and Quietness,”

• “Overall Rating.”

Scoring is modified such that for each of the six unchanged dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) will be calculated, the larger of which will be summed across these six dimensions to create a pre-normalized HCAHPS Base Score of 0–60 points (as compared to 0–80 points with the current eight dimensions). The pre-normalized HCAHPS Base Score will then be multiplied by % (1.3333333) and rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the six unchanged dimensions will be of equal weight, so that, as currently scored, the normalized HCAHPS Base Score will range from 0 to 80 points. HCAHPS Consistency Points will be calculated in the same

manner as the current method and will continue to range from 0 to 20 points. Like the Base Score, the Consistency Points Score will consider scores across the six unchanged dimensions of the Person and Community Engagement domain. The final element of the scoring formula, which will remain unchanged from the current formula, will be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points Score for a total score that ranges from 0 to 100 points. The method for calculating the performance standards for the six dimensions will remain unchanged. We refer readers to the Hospital Inpatient Value-Based Purchasing Program final rule (76 FR 26511 through 26512) for our methodology for calculating performance standards. The estimated performance standards for the six unchanged dimensions for the FY 2029 program year are set out in Table V.J.9.

**TABLE V.J.9.: NEWLY ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2029 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN**

| HCAHPS Survey Dimension* <sup>1</sup> | Floor (minimum) | Achievement Threshold (50 <sup>th</sup> percentile) | Benchmark (mean of top decile) |
|---------------------------------------|-----------------|-----------------------------------------------------|--------------------------------|
| Communication with Nurses             | 51.98           | 77.86                                               | 86.20                          |
| Communication with Doctors            | 55.49           | 77.63                                               | 85.67                          |
| Responsiveness of Hospital Staff**    | X               | X                                                   | X                              |
| Communication about Medicines         | 38.46           | 59.17                                               | 69.76                          |
| Hospital Cleanliness & Quietness      | 36.34           | 63.29                                               | 76.24                          |
| Discharge Information                 | 65.06           | 86.09                                               | 91.15                          |
| Care Transition**                     | X               | X                                                   | X                              |
| Overall Rating of Hospital            | 35.39           | 69.14                                               | 82.78                          |

<sup>1</sup> Includes IPPS hospitals with 100+ completed surveys from patients discharged between October 2024 and September 2025.

\*We note that the numerical values for the performance standards for the HCAHPS Survey in this proposed rule represent estimates based on the most recently available data. These estimates are based on 10/01/2024–09/30/2025 data.

\*\* In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69507 and 69508), we finalized the policy to only score on the six unchanged dimensions of the original HCAHPS Survey for the FY 2029 program year while the updates to the survey are publicly reported on in the Hospital Inpatient Quality Reporting Program for the statutorily required one year. Therefore, we are not reporting performance standards for the dimensions that are unscored.

The previously established performance standards for Clinical

Outcomes domain and the Efficiency and Cost Reduction domain measures

are set out in Table V.J.10. for the FY 2030 program year.

**TABLE V.J.10.: PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2030 PROGRAM YEAR**

| Measure Short Name                          | Achievement Threshold                                                                              | Benchmark                                                                                                              |
|---------------------------------------------|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>Clinical Outcomes Domain</b>             |                                                                                                    |                                                                                                                        |
| MORT-30-AMI                                 | 0.872557                                                                                           | 0.892486                                                                                                               |
| MORT-30-HF                                  | 0.87823                                                                                            | 0.908997                                                                                                               |
| MORT-30-PN                                  | 0.805539                                                                                           | 0.849398                                                                                                               |
| MORT-30-COPD                                | 0.902955                                                                                           | 0.924203                                                                                                               |
| MORT-30-CABG                                | 0.972039                                                                                           | 0.981517                                                                                                               |
| COMP-HIP-KNEE*                              | 0.034757                                                                                           | 0.024614                                                                                                               |
| <b>Efficiency and Cost Reduction Domain</b> |                                                                                                    |                                                                                                                        |
| MSPB*                                       | Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period. | Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period. |

\* Lower values represent better performance.

The previously established performance standards for Clinical

Outcomes domain and the Efficiency and Cost Reduction domain measures

are set out in Table V.J.11. for the FY 2031 program year.

**TABLE V.J.11.: PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2031 PROGRAM YEAR**

| Measure Short Name                          | Achievement Threshold                                                                              | Benchmark                                                                                                              |
|---------------------------------------------|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>Clinical Outcomes Domain</b>             |                                                                                                    |                                                                                                                        |
| MORT-30-AMI                                 | 0.877505                                                                                           | 0.895401                                                                                                               |
| MORT-30-HF                                  | 0.882399                                                                                           | 0.912122                                                                                                               |
| MORT-30-PN                                  | 0.831029                                                                                           | 0.870506                                                                                                               |
| MORT-30-COPD                                | 0.90878                                                                                            | 0.929579                                                                                                               |
| MORT-30-CABG                                | 0.974896                                                                                           | 0.983693                                                                                                               |
| COMP-HIP-KNEE*                              | 0.036571                                                                                           | 0.025288                                                                                                               |
| <b>Efficiency and Cost Reduction Domain</b> |                                                                                                    |                                                                                                                        |
| MSPB*                                       | Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period. | Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period. |

\* Lower values represent better performance.

c. Newly Established Performance Standards for Certain Measures for the FY 2032 Program Year

As discussed previously, we have adopted certain measures for the Clinical Outcomes domain (MORT-30-AMI, MORT-30-HF, MORT-30-PN, MORT-30-COPD, MORT-30-CABG, and COMP-HIP-KNEE) and the Efficiency and Cost Reduction domain (MSPB Hospital) for future program

years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient Value-Based Purchasing Program final rule (76 FR 26511 through 26512), which is codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2032 program year

for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in Table V.J.12.

**TABLE V.J.12.: NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2032 PROGRAM YEAR**

| Measure Short Name                          | Achievement Threshold                                                                              | Benchmark                                                                                                              |
|---------------------------------------------|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>Clinical Outcomes Domain</b>             |                                                                                                    |                                                                                                                        |
| MORT-30-AMI**                               | 0.881686                                                                                           | 0.899183                                                                                                               |
| MORT-30-HF**                                | 0.887519                                                                                           | 0.915618                                                                                                               |
| MORT-30-PN**                                | 0.846031                                                                                           | 0.882679                                                                                                               |
| MORT-30-COPD**                              | 0.911638                                                                                           | 0.930897                                                                                                               |
| MORT-30-CABG**                              | 0.976958                                                                                           | 0.984987                                                                                                               |
| COMP-HIP-KNEE*                              | 0.039655                                                                                           | 0.028874                                                                                                               |
| <b>Efficiency and Cost Reduction Domain</b> |                                                                                                    |                                                                                                                        |
| MSPB*                                       | Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period. | Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period. |

\* Lower values represent better performance.

\*\* As discussed in section IX.B.2. of the preamble of this proposed rule, we are proposing modifications and providing notice of technical updates to the five mortality measures in the Clinical Outcomes domain beginning with the FY 2032 program year.

**BILLING CODE 4120-01-C**

**K. Hospital-Acquired Condition (HAC) Reduction Program**

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50709) for a general overview of the HAC Reduction Program and a

detailed discussion of the statutory basis for the program. We also refer readers to 42 CFR 412.170 through 412.172 for codified HAC Reduction Program requirements. For additional information about the HAC Reduction Program measures and maintenance of

technical specifications, we refer readers to the FY 2026 IPPS/LTCH PPS final rule (90 FR 36963 through 36967).

We are not making any proposals or updates for the HAC Reduction Program in this proposed rule. We refer readers to section I.G.8. of Appendix A of this

proposed rule for an updated estimate of the proportion of hospitals in the worst performing quartile of the Total HAC Scores for the FY 2027 HAC Reduction Program.

#### *L. Rural Community Hospital Demonstration Program*

##### 1. Introduction

The Rural Community Hospital Demonstration was originally authorized by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). The demonstration has been extended three times since the original 5-year period mandated by the MMA, each time for an additional 5 years. These extensions were authorized by sections 3123 and 10313 of the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148), section 15003 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) enacted in 2016, and most recently, by section 128 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which also reauthorized the RCHD for five years. Later in this section we summarize the status of the demonstration program and the current methodologies for implementation and calculating budget neutrality.

##### 2. Background

Section 410A(a) of the MMA required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Our policy for implementing the 5-year extension period authorized by the CAA, 2021 follows upon the previous extensions under the ACA and the Cures Act. Section 410A of the MMA

initially required a 5-year period of performance. Subsequently, sections 3123 and 10313 of the ACA (Pub. L. 111–148) required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. In addition, the ACA (Pub. L. 111–148) limited the number of hospitals participating to no more than 30. Section 15003 of the Cures Act (Pub. L. 114–255) required a 10-year extension period in place of the 5-year extension period under the ACA (Pub. L. 111–148), thereby extending the demonstration for another 5 years. Section 128 of CAA, 2021 (Pub. L. 116–260), in turn, revised the statute to indicate a 15-year extension period, instead of the 10-year extension period mandated by the Cures Act (Pub. L. 114–255). The FY 2023 IPPS proposed and final rules (87 FR 28454 through 28458, and 87 FR 49138 through 49142, respectively) describe hospitals entering into and withdrawing from the demonstration with these re-authorizations. As of March 2026, there are 27 hospitals participating in the demonstration.

##### 2. Budget Neutrality

###### a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of the MMA (Pub. L. 108–173) requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount that the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as “budget neutrality.” Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. We note that the payment methodology for this demonstration, that is, cost-based payments to participating small rural hospitals, made it unlikely that increased Medicare outlays would produce an offsetting reduction to Medicare expenditures elsewhere. Therefore, in the IPPS final rules spanning the period from FY 2005 through FY 2016, we have adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration program, applying budget neutrality across the payment

system as a whole rather than merely across the participants in the demonstration program. We applied a different methodology for FY 2017, with the demonstration expected to end prior to the Cures Act extension. As described in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the statutory language of the budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

We resumed this methodology of offsetting demonstration costs against the national payment rates in the IPPS final rules from FY 2018 through FY 2026. Please see the FY 2026 IPPS/LTCH PPS final rule for a description of how we applied the budget neutrality requirement for these fiscal years (90 FR 36967 through 36969).

###### b. General Budget Neutrality Methodology

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, “as submitted” cost reports for the hospitals participating in that year. Updated factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for

the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. For historical development and modifications to this methodology, see 81 FR 57034 through 57037.

We note that we have calculated this difference for FYs 2005 through 2020 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

#### c. Budget Neutrality Methodology for the Extension Period Authorized by CAA, 2021

For the most-recently enacted extension period, under the CAA, 2021, we have continued upon the general budget neutrality methodology used in previous years, as described previously in the citations to earlier IPPS final rules.

Under the general methodology used in previous years, we have estimated the costs of the demonstration for the upcoming fiscal year, and proposed to incorporate the estimate into the budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. We are conducting this estimate for FY 2027 based on the 30 participating hospitals for cost report periods ending in CY2024. However, due to timing issues with the addition of 11 new hospitals in 2025, we are not yet able to finalize the estimated FY 2027 costs of the demonstration at this time. We anticipate that all of the historical “as submitted” cost reports needed to formulate estimated demonstration costs for FY 2027 and FY 2028 will be available in advance of the FY 2028 IPPS/LTCH PPS proposed rule and we will be able to finalize estimated demonstration costs for both FY 2027 and FY 2028.

As noted, in previous years we have also calculated the difference between the actual costs of the demonstration and estimated costs of the demonstration for FYs 2005 through 2020 as determined from finalized cost reports. We intend to continue with this approach and anticipate that we will be able to determine the actual costs for the demonstration for FY 2021 and FY 2022 from finalized cost reports in advance of the FY 2028 IPPS/LTCH PPS proposed rule. Consistent with our methods in previous years these differences will be applied to the estimated costs of the demonstration when determining the FY 2027 and FY 2028 budget neutrality offsets.

As we are not yet able to finalize the FY 2027 estimated costs of the demonstration at this time, we are not proposing to apply a budget neutrality offset to the FY 2027 IPPS/LTCH PPS proposed rule. Rather, we are proposing to apply budget neutrality offsets for both FY 2027 and FY 2028 to the national IPPS rates in the FY 2028 IPPS/LTCH PPS proposed rule. We will also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration. We invite public comments.

### VI. Proposed Changes to the IPPS for Capital-Related Costs

#### A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

$$(\text{Standard Federal Rate}) \times (\text{DRG Weight}) \\ \times (\text{Geographic Adjustment Factor (GAF)}) \times (\text{COLA for hospitals located in Alaska and Hawaii}) \times (1 +$$

*Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).*

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

#### B. Additional Provisions

##### 1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of \$5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

##### 2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

##### 3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico

beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Pub. L. 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

### *C. Proposed Annual Update for FY 2027*

The proposed annual update to the national capital Federal rate, as provided in 42 CFR 412.308(c), for FY 2027 is discussed in section III. of the Addendum to this FY 2027 IPPS/LTCH PPS proposed rule.

## **VII. Proposed Changes for Hospitals Excluded From the IPPS**

### *A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2027*

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under

§ 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (formerly classified as "Subclause II LTCs") also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs.

Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45207), we finalized the use of the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2022 and subsequent fiscal years. As discussed in section IV. of the preamble of the FY 2026 IPPS/LTCH PPS final rule (90 FR 36859 through 36866), we rebased and revised the IPPS operating basket to a 2023 base year. Therefore, we used the percentage increase in the 2023-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2026.

For this FY 2027 IPPS/LTCH PPS proposed rule, based on IGI's 2025 fourth quarter forecast, we estimate that the 2023-based IPPS operating market basket percentage increase for FY 2027 is 3.2 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2027 rate-of-increase percentage that will be applied to the FY 2026 target amounts in order to calculate the FY 2027 target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 3.2 percent, in accordance with the applicable regulations at 42 CFR 413.40. Furthermore, we are proposing that if

more recent data become available for the FY 2027 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket percentage increase for FY 2027.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as "extended neoplastic disease care hospitals") for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4), (for additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of total Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2027, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2027, the proposed update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3), which is estimated to be the proposed percentage increase in the 2023-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2027 is 3.2 percent, which is based on IGI's fourth quarter 2025 forecast. Furthermore, we are proposing that if more recent data become available for the FY 2027 IPPS/LTCH PPS final rule,



we would use such data, if appropriate, to calculate the IPPS operating market basket rate of increase for FY 2027.

## *B. Critical Access Hospitals (CAHs)*

### 1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

### 2. Frontier Community Health Integration Project Demonstration

#### a. Introduction

The Frontier Community Health Integration Project Demonstration was originally authorized by section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). The demonstration has been extended by section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) for an additional 5 years. In this proposed rule, we are summarizing the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality for the demonstration extension period.

#### b. Background and Overview

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), section 123 of the Medicare Improvements for Patients and Providers Act of 2008, as amended by section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled “Demonstration Project on Community Health Integration Models in Certain Rural Counties,” and commonly known as the Frontier Community Health Integration Project (FCHIP) Demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is a Medicare Rural Hospital

Flexibility Program (MRHFP) grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the state are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. In addition, section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration. CMS selected CAHs to participate in four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Section 123 of Public Law 110–275 initially required a 3-year period of performance. The FCHIP Demonstration began on August 1, 2016, and concluded on July 31, 2019 (referred to in this section of the proposed rule as the “initial period”). Subsequently, section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) extended the demonstration by 5 years (referred to in this section of the proposed rule as the “extension period”). The Secretary is required to conduct the demonstration for an additional 5-year period. CAHs participating in the demonstration project during the extension period began such participation in their cost reporting year that began on or after January 1, 2022.

As described in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), 10 CAHs were selected for participation in the demonstration initial period. The selected CAHs were located in three states—Montana, Nevada, and North Dakota—and participated in three of the four interventions identified in the FY 2025 IPPS/LTCH PPS final rule. Each CAH was allowed to participate in more than

one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS concluded that the initial period of the FCHIP Demonstration (covering the performance period of August 1, 2016, to July 31, 2019) had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration.

Section 129 of Public Law 116–260, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, five have elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing three of the four interventions. The eligible CAH participants elected to change the number of interventions and payment waivers they would participate in during the extension period. CMS accepted and approved the CAHs intervention and payment waiver updates. For the extension period, five CAHs are participants in the telehealth intervention, three CAHs are participants in the skilled nursing facility/nursing facility bed intervention, and three CAHs are participants in the ambulance services intervention. As with the initial period, each CAH was allowed to participate in more than one of the interventions during the extension period. None of the selected CAHs are participants in the home health intervention, which was the fourth intervention.

#### c. Intervention Payment and Payment Waivers

As described in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), CMS waived certain Medicare rules for CAHs participating in the demonstration initial period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility (SNF/NF) beds expansion. The payments and payment waiver provisions only apply if the CAH is a participant in the associated intervention. CMS Intervention Payment and Payment Waivers for the demonstration extension period consist of the following:

#### (1) Telehealth Services Intervention Payments

CMS waives section 1834(m)(2)(B) of the Act, which specifies the facility fee to the originating site for Medicare telehealth services. CMS modifies the facility fee payment specified under section 1834(m)(2)(B) of the Act to make reasonable cost-based reimbursement to the participating CAH where the participating CAH serves as the originating site for a telehealth service furnished to an eligible telehealth individual, as defined in section 1834(m)(4)(B) of the Act. CMS reimburses the participating CAH serving as the originating site at 101 percent of its reasonable costs for overhead, salaries and fringe benefits associated with telehealth services at the participating CAH. CMS does not fund or provide reimbursement to the participating CAH for the purchase of new telehealth equipment.

CMS waives section 1834(m)(2)(A) of the Act, which specifies that the payment for a telehealth service furnished by a distant site practitioner is the same as it would be if the service had been furnished in-person. CMS modifies the payment amount specified for telehealth services under section 1834(m)(2)(A) of the Act to make reasonable cost-based reimbursement to the participating CAH for telehealth services furnished by a physician or practitioner located at distant site that is a participating CAH that is billing for the physician or practitioner professional services. Whether the participating CAH has or has not elected Optional Payment Method II for outpatient services, CMS would pay the participating CAH 101 percent of reasonable costs for telehealth services when a physician or practitioner has reassigned their billing rights to the participating CAH and furnishes telehealth services from the participating CAH as a distant site practitioner. This means that participating CAHs that are billing under the Standard Method on behalf of employees who are physicians or practitioners (as defined in section 1834(m)(4)(D) and (E) of the Act, respectively) would be eligible to bill for distant site telehealth services furnished by these physicians and practitioners. Additionally, CAHs billing under the Optional Method would be reimbursed based on 101 percent of reasonable costs, rather than paid based on the Medicare physician fee schedule, for the distant site telehealth services furnished by physicians and practitioners who have reassigned their billing rights to the CAH. For distant site telehealth

services furnished by physicians or practitioners who have not reassigned billing rights to a participating CAH, payment to the distant site physician or practitioner would continue to be made as usual under the Medicare physician fee schedule. Except as described herein, CMS does not waive any other provisions of section 1834(m) of the Act for purposes of the telehealth services intervention payments, including the scope of Medicare telehealth services as established under section 1834(m)(4)(F) of the Act.

#### (2) Ambulance Services Intervention Payments

CMS waives 42 CFR 413.70(b)(5)(i)(D) and section 1834(l)(8) of the Act, which provides that payment for ambulance services furnished by a CAH, or an entity owned and operated by a CAH, is 101 percent of the reasonable costs of the CAH or the entity in furnishing the ambulance services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. The participating CAH would be paid 101 percent of reasonable costs for its ambulance services regardless of whether there is any provider or supplier of ambulance services located within a 35-mile drive of the participating CAH or participating CAH-owned and operated entity. CMS would not make cost-based payment to the participating CAH for any new capital (for example, vehicles) associated with ambulance services. This waiver does not modify any other Medicare rules regarding or affecting the provision of ambulance services.

#### (3) SNF/NF Beds Expansion Intervention Payments

CMS waives 42 CFR 485.620(a), 42 CFR 485.645(a)(2), and section 1820(c)(2)(B)(iii) of the Act which limit CAHs to maintaining no more than 25 inpatient beds, including beds available for acute inpatient or swing bed services. CMS waives 1820(f) of the Act permitting designating or certifying a facility as a critical access hospital for which the facility at any time is furnishing inpatient beds which exceed more than 25 beds. Under this waiver, if the participating CAH has received swing bed approval from CMS, the participating CAH may maintain up to ten additional beds (for a total of 35 beds) available for acute inpatient or swing bed services; however, the participating CAH may only use these

10 additional beds for nursing facility or skilled nursing facility level of care. CMS would pay the participating CAH 101 percent of reasonable costs for its SNF/NF services furnished in the 10 additional beds.

#### d. Budget Neutrality

##### (1) Budget Neutrality Requirement

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), we finalized a policy to address the budget neutrality requirement for the demonstration initial period. As explained in the FY 2022 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms, meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration initial period of performance in the FY 2022 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), we adopted the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110 275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period are not sufficiently offset by reductions elsewhere, we would recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2023 IPPS/LTCH PPS final rule, because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration extension period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is

found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2023 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented and does not identify the range across which aggregate payments must be held equal.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy that in the event the demonstration extension period is found not to have been budget neutral, any excess costs would be recouped within one fiscal year. We explained our belief that this policy is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period.

#### (2) FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy to adopt the budget neutrality methodology and analytical approach used during the demonstration initial period to ensure budget neutrality for the extension period. The analysis of budget neutrality during the initial period of the demonstration identified both the costs related to providing the intervention services under the FCHIP Demonstration and any potential

downstream effects of the intervention-related services, including any savings that may have accrued.

The budget neutrality analytical approach for the demonstration initial period incorporated two major data components: (1) Medicare cost reports; and (2) Medicare administrative claims. As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS computed the cost of the demonstration for each fiscal year of the demonstration initial period using Medicare cost reports for the participating CAHs, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention services.

In addition, in order to capture the full impact of the interventions, CMS developed a statistical modeling, Difference-in-Difference (DiD) regression analysis to estimate demonstration expenditures and compute the impact of expenditures on the intervention services by comparing cost data for the demonstration and non-demonstration groups using Medicare administrative claims across the demonstration period of performance under the initial period of the demonstration. The DiD regression analysis would compare the direct cost and potential downstream effects of intervention services, including any savings that may have accrued, during the baseline and performance period for both the demonstration and comparison groups.

Second, the Medicare administrative claims analysis would be reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. We would estimate the costs of the demonstration using "as submitted" cost reports for each hospital's financial fiscal year participation within each of the demonstration extension period performance years. Each CAH has its own Medicare cost report end date applicable to the 5-year period of performance for the demonstration extension period. The cost report is structured to gather costs, revenues and statistical data on the provider's financial fiscal period. As a result, we finalized a policy in the FY 2023 IPPS/LTCH PPS final rule that we would determine the final budget neutrality results for the demonstration extension once complete data is available for each CAH for the demonstration extension period.

e. Policies for Implementing the 5-Year Extension and Provisions Authorized by Section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260)

As stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

#### f. Total Budget Neutrality Offset Amount for FY 2027

At this time, for the FY 2027 IPPS/LTCH PPS proposed rule, while this discussion represents our anticipated approach to assessing the financial impact of the demonstration extension period based on upon receiving data for the full demonstration extension period, we may update and/or modify the FCHIP Demonstration budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. Therefore, we do not propose to apply a budget neutrality payment offset to payments to CAHs in FY 2027. This policy would have no impact for any national payment system for FY 2027.

### VIII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2027

#### A. Background of the LTCH PPS

##### 1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care

hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital that has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.

Section 1886(d)(1)(B)(iv)(II) of the Act also provided an alternative definition of LTCHs (“subclause II” LTCHs). However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former “subclause II” LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as “extended neoplastic disease care hospitals,” to be paid as hospitals that were formally classified as “subclause (II)” LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a “per discharge” system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resource use and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002, **Federal Register** (67 FR 55954), we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA. For the initial implementation of the LTCH PPS (FYs 2003 through 2007), the system used information from LTCH patient records to classify patients into distinct long-term care-diagnosis-related groups (LTCDRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity-long-term care-diagnosis related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA)

(Pub. L. 97–248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable-cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital’s updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002, final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002, final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH’s total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs’ cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002, final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002, final rule for a comprehensive discussion of the research and data that supported the

establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the “site neutral” payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (“the Cures Act”) (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to (82 FR 38299).)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-percent threshold policy under 42 CFR 412.538, which was a payment adjustment that was applied to payments for Medicare patient LTCH discharges when the number of such patients originating from any single referring hospital was in excess of the applicable threshold for given cost reporting period.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

## 2. Criteria for Classification as an LTCH

### a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

### b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b1 (note)) (Statewide-all payer systems, subject to the rate-of increase test at section 1814(b) of the Act), or section 3021 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

## 3. Limitation on Charges to Beneficiaries

In the August 30, 2002, final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as

specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

### *B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2027*

#### 1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

Under both the IPPS and the LTCH PPS, the DRG-based classification system uses information on the claims for inpatient discharges to classify patients into distinct groups (for example, DRGs) based on clinical characteristics and expected resource needs. When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. We referred to this patient classification system as the “long-term care diagnosis-related groups

(LTC–DRGs).” As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), we adopted the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O, applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. As noted previously, we adopted the same DRG patient classification system utilized at that time under the IPPS. The MS–DRG classifications are updated annually, which has resulted in the number of MS–DRGs changing over time. For FY 2027, there would be 768 MS–DRG, and by extension, MS–LTC–DRG, groupings based on the proposed changes, as discussed in section II.C. of the preamble of this proposed rule.

Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA. That is, we assign an appropriate weight to the MS–LTC–DRGs to account for the differences in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCH patients.

## 2. Patient Classifications Into MS–LTC–DRGs

### a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The Grouper software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs) or are minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using the version ASC X12 5010 standard, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities (45 CFR 160.103) must comply with the adopted transaction standards and operating rules specified in subparts I through S

of part 162. Among other requirements, on or after January 1, 2012, covered entities are required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code sets when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.E.1. of the preamble of this proposed rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS*.

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

Medicare Administrative Contractors (MACs) enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are

designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain types of cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH Grouper software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The Grouper software used under the LTCH PPS is the same Grouper software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The Grouper software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

### b. Proposed Changes to the MS–LTC–DRGs for FY 2027

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this proposed rule, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2026 through September 30, 2027 (FY 2027), consistent with the proposed changes to specific MS–DRG classifications presented in section II.C. of the preamble of this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2027 are the same as the MS–DRGs being proposed for use under the IPPS for FY 2027. In addition, because the proposed MS–LTC–DRGs for FY 2027 are the same as the proposed MS–DRGs for FY 2027, the

other proposed changes that affect MS-DRG (and by extension MS-LTC-DRG) assignments under proposed Grouper Version 44, as discussed in section II.C. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD-10-CM/PCS coding system, are also applicable under the LTCH PPS for FY 2027.

### 3. Proposed Development of the FY 2027 MS-LTC-DRG Relative Weights

#### a. General Overview of the MS-LTC-DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. Under the LTCH PPS, relative weights for each MS-LTC-DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS-LTC-DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS-LTC-DRG that represents the resources needed by an average inpatient LTCH case in that MS-LTC-DRG. For example, cases in an MS-LTC-DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS-LTC-DRG with a relative weight of 1.

The established methodology to develop the MS-LTC-DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002, LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume or nonmonotonicity or both resulting from the adoption of the MS-LTC-DRGs. We also made a modification in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH

PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). We also adopted, beginning in FY 2023, a 10-percent cap policy on the reduction in a MS-LTC-DRG's relative weight in a given year. (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and nonmonotonicity or both, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550)). For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS-LTC-DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). For details on our adoption of the 10-percent cap policy, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49152 through 49154.).

For purposes of determining the MS-LTC-DRG relative weights, under our historical methodology, there are three different categories of MS-LTC-DRGs based on volume of cases within specific MS-LTC-DRGs: (1) MS-LTC-DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS-LTC-DRGs (that is, MS-LTC-DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section in Step 3 of our proposed methodology) and assigned the relative weight of the quintile); and (3) no-volume MS-LTC-DRGs that are cross-walked to other MS-LTC-DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS-LTC-DRG (as described later in this section in Step 8 of our proposed methodology). For FY 2027, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2027 MS-LTC-DRG relative weights.

#### b. Development of the MS-LTC-DRG Relative Weights for FY 2027

In this section, we present our proposed methodology for determining the MS-LTC-DRG relative weights for FY 2027. We first list and provide a brief description of our proposed steps for determining the FY 2027 MS-LTC-DRG relative weights. Later in this section, we discuss in greater detail

each step. We note that, as we did in FY 2026, we are proposing to use our historical relative weight methodology as described in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58898 through 58907), subject to a ten percent cap as described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49162).

- *Step 1—Prepare data for MS-LTC-DRG relative weight calculation.* In this step, we select and group the applicable claims data used in the development of the MS-LTC-DRG relative weights.

- *Step 2—Remove cases with a length of stay of 7 days or less.* In this step, we trim the applicable claims data to remove cases with a length of stay of 7 days or less.

- *Step 3—Establish low-volume MS-LTC-DRG quintiles.* In this step, we employ our established quintile methodology for low-volume MS-LTC-DRGs (that is, MS-LTC-DRGs with fewer than 25 cases).

- *Step 4—Remove statistical outliers.* In this step, we trim the applicable claims data to remove statistical outlier cases.

- *Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).* In this step, we adjust the number of applicable cases in each MS-LTC-DRG (or low-volume quintile) for the effect of SSO cases.

- *Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative weights methodology.* In this step, we use our established hospital specific relative value (HSRV) methodology, which is an iterative process, to calculate the relative weights.

- *Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights.* In this step, we make adjustments that ensure that within each base MS-LTC-DRG, the relative weights increase by MS-LTC-DRG severity.

- *Step 8—Determine a relative weight for MS-LTC-DRGs with no applicable LTCH cases.* In this step, we cross-walk each no-volume MS-LTC-DRG to another MS-LTC-DRG for which we calculated a relative weight.

- *Step 9—Budget neutralize the uncapped relative weights.* In this step, to ensure budget neutrality in the annual update to the MS-LTC-DRG classifications and relative weights, we adjust the relative weights by a normalization factor and a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by the updates to the MS-LTC-DRG classifications and relative weights.

- *Step 10—Apply the 10-percent cap to decreases in MS-LTC-DRG relative*



*weights.* In this step we limit the reduction of the relative weight for a MS–LTC–DRG to 10 percent of its prior year value. This 10-percent cap does not apply to zero-volume MS–LTC–DRGs or low-volume MS–LTC–DRGs.

- *Step 11—Budget neutralize the application of the 10-percent cap policy.* In this step, to ensure budget neutrality in the application of the MS–LTC–DRG cap policy, we adjust the relative weights by a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by our application of the cap to the MS–LTC–DRG relative weights.

We next describe each of the 11 proposed steps for calculating the proposed FY 2027 MS–LTC–DRG relative weights in greater detail.

#### Step 1—Prepare Data for MS–LTC–DRG Relative Weight Calculation

For this FY 2027 IPPS/LTCH PPS proposed rule, we obtained total charges from FY 2025 Medicare LTCH claims data from the December 2025 update of the FY 2025 MedPAR file and used proposed Version 44 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we are proposing that if better data become available, we would use those data and the finalized Version 44 of the GROUPER in establishing the FY 2027 MS–LTC–DRG relative weights in the final rule.

To calculate the FY 2027 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period. The COVID–19 PHE expired on May 11, 2023. Therefore, nearly all LTCH PPS cases in FY 2025 were subject to the dual rate LTCH PPS payment structure. However, a small number of FY 2025 LTCH PPS cases (those with admission dates on or before May 11, 2023) were subject to the CARES Act waiver and were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. Therefore, for purposes of setting rates for LTCH PPS standard Federal rate cases for FY 2027 (including MS–LTC–DRG relative weights), we are proposing to identify FY 2025 cases that meet the statutory patient criteria depending on date of admission as follows. First, we propose

to use LTCH PPS cases in the FY 2025 MedPAR file with an admission date after May 11, 2023, that met the criteria for exclusion from the site neutral payment rate under § 412.522(b) and were paid the LTCH PPS standard Federal rate in FY 2025 (based on the claim payment amount). Second, we propose to also use LTCH PPS cases in the FY 2025 MedPAR file with an admission date on or before May 11, 2023, that would have met the criteria for exclusion from the site neutral payment rate if the CARES Act waiver had not been in effect. For these cases we relied on our historical process for identifying cases that would have met the criteria for exclusion from the site neutral payment rate rather than how those cases were paid in FY 2025. This process is explained in full detail in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69425).

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of “1” in the MedPAR files.

In summary, in general, we identified the claims data used in the development of the FY 2027 MS–LTC–DRG relative weights in this proposed rule by trimming claims data that were paid the site neutral payment rate or would have been paid the site neutral payment rate had the provisions of the CARES Act not been in effect. We trimmed the claims data of all inclusive rate providers reported in the December 2025 update of the FY 2025 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the December 2025 update of the FY 2025 MedPAR file, but had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy.

We used the remaining data (that is, the applicable LTCH data) in the subsequent proposed steps to calculate the proposed MS–LTC–DRG relative weights for FY 2027.

#### Step 2—Remove Cases With a Length of Stay of 7 Days or Less

The next step in our proposed calculation of the proposed FY 2027 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the proposed FY 2027 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the proposed FY 2027 MS–LTC–DRG relative weights, we are proposing to remove LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

#### Step 3—Establish Low-Volume MS–LTC–DRG Quintiles

To account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we are proposing to continue to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the “low-volume MS–LTC–DRGs” (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)).

In this proposed rule, based on the best available data (that is, the December 2025 update of the FY 2025 MedPAR file), we identified 245 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles. We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles



by sorting the low-volume MS-LTC-DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this proposed rule, the number of MS-LTC-DRGs with less than 25 applicable LTCH cases was evenly divisible by 5. The quintiles each contained 49 MS-LTC-DRGs ( $245/5 = 49$ ). We are proposing that in the final rule, if the number of MS-LTC-DRGs with less than 25 applicable LTCH cases in the best available data is not evenly divisible by 5, we would employ our historical methodology of assigning each remainder low-volume MS-LTC-DRG to the low-volume quintile that contains an MS-LTC-DRG with an average charge closest to that of the remainder low-volume MS-LTC-DRG. In cases where these initial assignments of low-volume MS-LTC-DRGs to quintiles results in nonmonotonicity within a base-DRG, we are proposing to make adjustments to the resulting low-volume MS-LTC-DRGs to preserve monotonicity, as discussed in Step 7 of our proposed methodology.

To determine the FY 2027 relative weights for the low-volume MS-LTC-DRGs, consistent with our historical practice, we are proposing to use the five low-volume quintiles described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in Step 6 of our proposed methodology. We assigned the same relative weight and average length of stay to each of the low-volume MS-LTC-DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS-LTC-DRGs with a low volume of applicable LTCH cases would vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS-LTC-DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS-LTC-DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

For this proposed rule, we are providing the list of the composition of the proposed low volume-quintiles for low-volume MS-LTC-DRGs in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> to

streamline the information made available to the public that is used in the annual development of Table 11.

#### Step 4—Remove Statistical Outliers

The next step in our proposed calculation of the FY 2027 MS-LTC-DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS-LTC-DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS-LTC-DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, in each set of claims, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this proposed rule, we refer to these cases as “trimmed applicable LTCH cases.”

#### Step 5—Adjust Charges for the Effects of Short Stay Outliers (SSOs)

As the next step in the proposed calculation of the FY 2027 MS-LTC-DRG relative weights, consistent with our historical approach, we are proposing to adjust each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay of all cases grouped to the MS-LTC-DRG. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS-LTC-DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS-LTC-DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the FY 2027 MS-LTC-DRG relative weights would lower the relative weight for affected MS-LTC-DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS-LTC-DRG. This would result in an “underpayment” for non-SSO cases and an “overpayment” for SSO cases. Therefore, we propose to continue to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

#### Step 6—Calculate the Relative Weights on An Iterative Basis Using the Hospital-Specific Relative Value Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS-LTC-DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS-LTC-DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2027 IPPS/LTCH PPS proposed rule, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the MS-LTC-DRG relative weights for FY 2027. We believe that this method removes this hospital specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduced the impact of the variation in charges across providers on any particular MS-LTC-DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH).

The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs). In other words, by multiplying an LTCH's relative charge values by the LTCH's case-mix index, we account for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource-intensive than they would be at an LTCH with low average charges. For example, a \$10,000 charge for a case at an LTCH with an average adjusted charge of \$17,500 reflects a higher level of relative resource use than a \$10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of \$35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

Consistent with our historical relative weight methodology, we propose to calculate the FY 2027 MS-LTC-DRG relative weights using the HSRV methodology, which is an iterative process. Therefore, in accordance with our established methodology, for FY 2027, we are proposing to continue to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in Step 5 of our proposed methodology) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The average adjusted charge is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix-index value of 1.0 for each LTCH.

For each proposed MS-LTC-DRG, we calculated the FY 2027 relative weight

by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS-LTC-DRG (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent cases from Step 5 for each MS-LTC-DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent applicable LTCH cases from Step 5 for each MS-LTC-DRG). Using these recalculated MS-LTC-DRG relative weights, each LTCH's average relative weight for all of its SSO adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS-LTC-DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital specific case-mix-adjusted relative charge values are then used to calculate a new set of MS-LTC-DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

#### Step 7—Adjust the Relative Weights To Account for Nonmonotonically Increasing Relative Weights

The MS-DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as “without CC/MCC.” When data do not support the creation of three severity levels, the base MS-DRG is subdivided into either two levels or the base MS-DRG is not subdivided. The two-level subdivisions may consist of the MS-DRG with CC/MCC and the MS-DRG without CC/MCC. Alternatively, the other type of two-level-subdivision may consist of the MS-DRG with MCC and the MS-DRG without MCC.

In those base MS-LTC-DRGs that are split into either two or three severity levels, cases classified into the “without CC/MCC” MS-LTC-DRG are expected

to have a lower resource use (and lower costs) than the “with CC/MCC” MS-LTC-DRG (in the case of a two level split) or both the “with CC” and the “with MCC” MS-LTC-DRGs (in the case of a three-level-split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS-LTC-DRG, an MS-LTC-DRG with CC has a higher relative weight than one with MCC, or the MS-LTC-DRG “without CC/MCC” has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS-LTC-DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS-LTC-DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the proposed FY 2027 MS-LTC-DRG relative weights, consistent with our historical methodology, we are proposing to continue to combine MS-LTC-DRG severity levels within a base MS-LTC-DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2027 MS-LTC-DRG relative weights by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website.

#### Step 8—Determine a Relative Weight for MS-LTC-DRGs With no Applicable LTCH Cases

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the MS-LTC-DRGs for which there were no claims in the December 2025 update of the FY 2025 MedPAR file and, therefore, for which no charge data was available for these MS-LTC-DRGs. Because patients with a number of the diagnoses under these MS-LTC-DRGs may be

treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS-LTC-DRGs based on clinical similarity and relative costliness (with the exception of “transplant” MS-LTC-DRGs, “error” MS-LTC-DRGs, and MS-LTC-DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation referred to as the “psychiatric or rehabilitation” MS-LTC-DRGs), as discussed later in this section of the preamble of this proposed rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, we are proposing to cross-walk each no-volume proposed MS-LTC-DRG to another proposed MS-LTC-DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the “no-volume” proposed MS-LTC-DRG is assigned the same relative weight (and average length of stay) of the proposed MS-LTC-DRG to which it was cross-walked (as described in greater detail in this section of the preamble of this proposed rule).

Of the 768 proposed MS-LTC-DRGs for FY 2027, we identified 414 MS-LTC-DRGs for which there were no trimmed applicable LTCH cases. The 414 MS-LTC-DRGs for which there were no trimmed applicable LTCH cases includes the 11 “transplant” MS-LTC-DRGs, the 2 “error” MS-LTC-DRGs, and the 15 “psychiatric or rehabilitation” MS-LTC-DRGs, which are discussed in this section of this proposed rule, such that we identified 386 MS-LTC-DRGs that for which, we are proposing to assign a relative weight using our existing “no-volume” MS-LTC-DRG methodology (that is,  $414 - 11 - 2 - 15 = 386$ ). We are proposing to assign relative weights to each of the 386 no-volume MS-LTC-DRGs based on clinical similarity and relative costliness to 1 of the remaining 354 ( $768 - 414 = 354$ ) MS-LTC-DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2025 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the “cross-walked” MS-LTC-DRGs as one of the 354 MS-LTC-DRGs to which we cross-walked each of the 386 “no-volume” MS-LTC-DRGs.) Then, in general, we are proposing to assign the 386 no-volume MS-LTC-DRGs the relative weight of the cross-walked MS-LTC-DRG (when necessary, we made adjustments to account for nonmonotonicity).

We cross-walked the no-volume MS-LTC-DRG to a MS-LTC-DRG for which we calculated relative weights based on the December 2025 update of the FY 2025 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/R Y 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS-LTC-DRGs in FY 2027, the relative weights assigned based on the cross-walked MS-LTC-DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the proposed relative weight of the cross-walked MS-LTC-DRG as the relative weight for the no-volume MS-LTC-DRG such that both of these MS-LTC-DRGs (that is, the no-volume MS-LTC-DRG and the cross-walked MS-LTC-DRG) have the same relative weight (and average length of stay) for FY 2027. We note that, if the cross-walked MS-LTC-DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume MS-LTC-DRG as well. Similarly, if the MS-LTC-DRG to which the no-volume MS-LTC-DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS-LTC-DRG such that both of these MS-LTC-DRGs (that is, the no-volume MS-LTC-DRG and the cross-walked MS-LTC-DRG) have the same relative weight for FY 2027. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS-LTC-DRG resulted, additional adjustments are required to maintain monotonically increasing relative weights.)

For this proposed rule, we are providing the list of the no-volume MS-LTC-DRGs and the MS-LTC-DRGs to which each was cross-walked (that is, the cross-walked MS-LTC-DRGs) for FY 2027 in a supplemental data file for public use posted via the internet on the

CMS website for this proposed rule at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the proposed relative weights for the FY 2027 MS-LTC-DRGs with no applicable LTCH cases, we are providing the following example.

*Example:* There were no trimmed applicable LTCH cases in the FY 2025 MedPAR file that we are using for this proposed rule for proposed MS-LTC-DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that proposed MS-LTC-DRG 064 (Intracranial hemorrhage or cerebral infarction with MCC) is similar clinically and based on resource use to proposed MS-LTC-DRG 061. Therefore, we are proposing to assign the same relative weight (and average length of stay) of proposed MS-LTC-DRG 064 of 1.0495 for FY 2027 to proposed MS-LTC-DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS-LTC-DRGs with no volume would vary in the future. Consistent with our historical practice, we are proposing to use the best available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in the final rule.

For FY 2027, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following transplant MS-LTC-DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS-LTC-DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS-LTC-DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS-LTC-DRG 005); Liver Transplant without MCC (MS-LTC-DRG 006); Lung Transplant (MS-LTC-DRG 007); Simultaneous Pancreas, Islet Cell and Kidney Transplant (MS-LTC-DRG 008); Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis (MS-LTC-DRG 019); Pancreas or Islet Cell Transplant (MS-LTC-DRG 010); Kidney Transplant (MS-LTC-DRG 652); Kidney Transplant with Hemodialysis with MCC (MS-LTC-DRG 650), and Kidney Transplant with Hemodialysis without MCC (MS-LTC-DRG 651). This is because Medicare only covers these

procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these 11 transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are proposing to establish a relative weight of 0.0000 for the 2 “error” MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, we are proposing to establish a relative weight of 0.0000 for the following “psychiatric or rehabilitation” MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedures with Principal Diagnosis of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Intellectual Disability); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol, Drug Abuse or Dependence, Left AMA); MS–LTC–DRG 895 (Alcohol, Drug Abuse or Dependence with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol, Drug Abuse or Dependence without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol, Drug Abuse or Dependence without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). We are proposing to establish a relative weight of 0.0000 for these 15 “psychiatric or rehabilitation” MS–LTC–DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate would not be applicable for any LTCH discharges occurring in FY 2027, and as such payment under the LTCH PPS would be no longer be made in part

based on the LTCH PPS standard Federal payment rate for any discharges assigned to those MS–LTC–DRGs.

#### Step 9—Budget Neutralize the Uncapped Relative Weights

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the FY 2008 LTCH PPS final rule (72 FR 26881 and 26882)).

To achieve budget neutrality under the requirement at § 412.517(b), under our established methodology, for each annual update the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to continue to apply budget neutrality adjustments in determining the proposed FY 2027 MS–LTC–DRG relative weights so that our proposed update of the MS–LTC–DRG classifications and relative weights for FY 2027 are made in a budget neutral manner. For FY 2027, we are proposing to apply two budget neutrality factors to determine the MS–LTC–DRG relative weights. In this step, we describe the determination of the budget neutrality adjustment that accounts for the proposed update of the MS–LTC–DRG classifications and relative weights prior to the application of the ten-percent cap. In steps 10 and 11, we describe the application of the 10-percent cap policy (step 10) and the determination of the proposed budget neutrality factor that accounts for the application of the 10-percent cap policy (step 11).

In this proposed rule, to ensure budget neutrality for the proposed update to the MS–LTC–DRG classifications and relative weights prior to the application of the 10-percent cap (that is, uncapped relative weights), under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. Therefore, in the first step of our MS–LTC–DRG update budget neutrality methodology, for FY 2027, we

calculated and applied a proposed normalization factor to the recalibrated relative weights (the result of Steps 1 through 8 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the proposed normalization factor for FY 2027, we propose to use the following three steps: (1.a.) use the applicable LTCH cases from the best available data (that is, LTCH discharges from the FY 2025 MedPAR file) and group them using the proposed FY 2027 GROUPER (that is, Version 44 for FY 2027) and the proposed recalibrated FY 2027 MS–LTC–DRG uncapped relative weights (determined in Steps 1 through 8 discussed previously) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2026 GROUPER (Version 43) and FY 2026 MS–LTC–DRG relative weights in Table 11 of the FY 2026 IPPS/LTCH PPS final rule and calculate the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average case-mix index for FY 2026 (determined in Step 1.b.) by the average case-mix index for FY 2027 (determined in Step 1.a.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2027, each recalibrated MS–LTC–DRG uncapped relative weight is multiplied by the proposed normalization factor of 1.27379 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produces “normalized relative weights.”

In the second step of our MS–LTC–DRG update budget neutrality methodology, we calculated a proposed budget neutrality adjustment factor consisting of the ratio of estimated aggregate FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration to estimated aggregate payments for FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases after reclassification and recalibration. That is, for this proposed rule, for FY 2027, we propose to determine the budget neutrality adjustment factor using the following three steps: (2.a.) simulate estimated total FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the

uncapped normalized relative weights for FY 2027 and proposed GROUPER Version 44; (2.b.) simulate estimated total FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2026 GROUPER (Version 43) and the FY 2026 MS–LTC–DRG relative weights in Table 11 of the FY 2026 IPPS/LTCH PPS final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the proposed FY 2027 MS–LTC–DRG relative weights, each uncapped normalized relative weight is then multiplied by a proposed budget neutrality factor of 1.0037632 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology.

#### Step 10—Apply the 10-Percent Cap to Decreases in MS–LTC–DRG Relative Weights

To mitigate the financial impacts of significant year-to-year reductions in MS–LTC–DRGs relative weights, beginning in FY 2023, we adopted a policy that applies a budget neutral 10-percent cap on annual relative weight decreases for MS–LTC–DRGs with at least 25 applicable LTCH cases (§ 412.515(b)). Under this policy, in cases where CMS creates new MS–LTC–DRGs or modifies the MS–LTC–DRGs as part of its annual reclassifications resulting in renumbering of one or more MS–LTC–DRGs, the 10-percent cap does not apply to the relative weight for any new or renumbered MS–LTC–DRGs for the fiscal year. We refer readers to section VIII.B.3.b. of the preamble of the FY 2023 IPPS/LTCH PPS final rule with comment period for a detailed discussion on the adoption of the 10-percent cap policy (87 FR 49152 through 49154).

Applying the 10-percent cap to MS–LTC–DRGs with 25 or more cases results in more predictable and stable MS–LTC–DRG relative weights from year to year, especially for high-volume MS–LTC–DRGs that generally have the largest financial impact on an LTCH's operations. For this proposed rule, in cases where the relative weight for a MS–LTC–DRG with 25 or more applicable LTCH cases would decrease by more than 10-percent in FY 2027 relative to FY 2026, we are proposing to limit the reduction to 10-percent. Under this policy, we do not apply the 10 percent cap to the proposed low-volume MS–LTC–DRGs identified in Step 3 or the proposed no-volume MS–LTC–DRGs identified in Step 8.

Therefore, in this step, for each proposed FY 2027 MS–LTC–DRG with

25 or more applicable LTCH cases (excludes low-volume and zero-volume MS–LTC–DRGs) we compared its FY 2027 relative weight (after application of the proposed normalization and proposed budget neutrality factors determined in Step 9), to its FY 2026 MS–LTC–DRG relative weight. For any MS–LTC–DRG where the FY 2027 relative weight would otherwise have declined more than 10 percent, we established a proposed capped FY 2027 MS–LTC–DRG relative weight that is equal to 90 percent of that MS–LTC–DRG's FY 2026 relative weight (that is, we set the proposed FY 2027 relative weight equal to the FY 2026 weight  $\times$  0.90).

In section II.C. of the preamble of this proposed rule, we discuss our proposed changes to the MS–DRGs, and by extension the MS–LTC–DRGs, for FY 2027. As discussed previously, under our current policy, the 10-percent cap does not apply to the relative weight for any new or renumbered MS–LTC–DRGs. We are not proposing any changes to this policy for FY 2027, and as such any proposed new or renumbered MS–LTC–DRGs for FY 2027 would not be eligible for the 10-percent cap.

#### Step 11—Budget Neutralize Application of the 10-Percent Cap Policy

Under the requirement at existing § 412.517(b) that aggregate LTCH PPS payments will be unaffected by annual changes to the MS–LTC–DRG classifications and relative weights, consistent with our established methodology, we are proposing to continue to apply a budget neutrality adjustment to the MS–LTC–DRG relative weights so that the 10-percent cap on relative weight reductions (step 10) is implemented in a budget neutral manner. Therefore, we are proposing to determine the proposed budget neutrality adjustment factor for the 10-percent cap on relative weight reductions using the following three steps: (a) simulate estimated total FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed capped relative weights for FY 2027 (determined in Step 10) and proposed GROUPER Version 44; (b) simulate estimated total FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed uncapped relative weights for FY 2027 (determined in Step 9) and proposed GROUPER Version 44; and (c) calculate the ratio of these estimated total payments by dividing the value determined in step (b) by the value determined in step (a). In determining the proposed FY 2027 MS–

LTC–DRG relative weights, each capped relative weight is then multiplied by a proposed budget neutrality factor of 0.997832 (the value determined in step (c)) to achieve the budget neutrality requirement.

Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, proposed geometric mean length of stay, and proposed five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2027. We also are making available on the website the proposed MS–LTC–DRG relative weights prior to the application of the 10 percent cap on MS–LTC–DRG relative weight reductions and corresponding proposed cap budget neutrality factor.

#### C. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FY 2027

##### 1. Overview of Development of the Proposed LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 2027, that is, effective for LTCH discharges occurring on or after October 1, 2026, through September 30, 2027. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at 42 CFR 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002, LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate from FYs 2003

through 2015, and LTCH PPS standard Federal payment rate from FY 2016 through present, as implemented under 42 CFR 412.523(c)(3), we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2027 IPPS/LTCH PPS proposed rule, we present our proposed policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2027.

The proposed update to the LTCH PPS standard Federal payment rate for FY 2027 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2027 are discussed in this section, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2027 as required by the statute (as discussed in section IX.C.2.c. of the preamble of this proposed rule). We are proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2027 on estimated aggregate LTCH PPS payments, in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B. of the Addendum to this proposed rule).

## 2. Proposed FY 2027 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

### a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2022-based LTCH market basket for use under the LTCH PPS beginning in FY 2025. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2022-based LTCH market basket, we refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69435 through 69455).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with

such adjustments as a “rate year.” We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term “fiscal year” (FY) rather than “rate year” (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as “rate year,” consistent with our change in the terminology used under the LTCH PPS from “rate year” to “fiscal year,” for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use “fiscal year” rather than “rate year” for 2011 and subsequent years.

### b. Proposed Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2027

As previously noted, we adopted the 2022-based LTCH market basket for use under the LTCH PPS beginning in FY 2025. The 2022-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of LTCHs. For additional details on the development of the 2022-based LTCH market basket, we refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69435 through 69455). We continue to believe that the 2022-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2025 IPPS/LTCH PPS final rule. Therefore, in this proposed rule, we are proposing to use the 2022-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2027.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A), as applicable. Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by “the productivity adjustment” described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in

annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). The U.S. Department of Labor’s Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) is published by BLS as private nonfarm business total factor productivity ((TFP) previously referred to as multifactor productivity).<sup>156</sup> We refer readers to [www.bls.gov/productivity](http://www.bls.gov/productivity) for the BLS historical published TFP data. A complete description of IGI’s TFP projection methodology is available on the CMS website at <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information>. Section 1886(m)(3)(A)(ii) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the “other adjustment” described in section 1886(m)(4)(F) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

### c. Proposed Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, requires that a 2.0 percentage points reduction be applied to any update under 42 CFR 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP under 42 CFR 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides

<sup>156</sup> <https://www.bls.gov/productivity/notices/2021/mfp-to-tfp-term-change.htm>



that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at 42 CFR 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section X.E. of the preamble of this proposed rule.)

**d. Proposed Annual Market Basket Update Under the LTCH PPS for FY 2027**

Consistent with our historical practice, we estimate the market basket percentage increase and the productivity adjustment based on IHS Global Inc.'s (IGI's) forecast using the most recent available data. Based on IGI's fourth quarter 2025 forecast, the proposed FY 2027 market basket percentage increase for the LTCH PPS using the 2022-based LTCH market basket is 3.2 percent. The proposed productivity adjustment for FY 2027 based on IGI's fourth quarter 2025 forecast is 0.8 percentage point.

For FY 2027, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the FY 2027 market basket percentage increase by the FY 2027 productivity adjustment. To determine the proposed market basket update for LTCHs for FY 2027 we subtracted the proposed FY 2027 productivity adjustment from the proposed FY 2027 market basket percentage increase. (For additional details on our established methodology for adjusting the market basket percentage increase by the productivity adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).) In addition, for FY 2027, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments

required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points.

In this FY 2027 IPPS/LTCH PPS proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2027 market basket percentage increase of 3.2 percent (based on IGI's fourth quarter 2025 forecast of the 2022-based LTCH market basket) by the proposed FY 2027 productivity adjustment of 0.8 percentage point (based on IGI's fourth quarter 2025 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we are proposing to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2027 of 2.4 percent (that is, the proposed LTCH PPS market basket percentage increase of 3.2 percent less the proposed productivity adjustment of 0.8 percentage point). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), we are proposing to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.4 percent (that is, the proposed 2.4 percent LTCH market basket update minus 2.0 percentage points) for FY 2027 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, we also are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket percentage increase and productivity adjustment), we would use such data, if appropriate, to determine the FY 2027 market basket percentage increase and productivity adjustment in the final rule. We note that, consistent with historical practice, we are also proposing to adjust the FY 2027 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B.6. of the Addendum to this proposed rule).

**IX. Proposed Quality Data Reporting Requirements for Specific Providers**

**A. Overview**

In section IX. of the preamble of this proposed rule, we are seeking comment on and proposing changes to the

following Medicare quality reporting programs:

- In section IX.B. of the preamble of this proposed rule, we have the following crosscutting quality program proposals or requests for comment:

++ Proposed Adoption of the Advance Care Planning Electronic Clinical Quality Measure for use in the Hospital Inpatient Quality Reporting Program, PPS-Exempt Cancer Hospital Quality Reporting Program, and Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (previously known as the Medicare EHR Incentive Program).

++ Proposed Modifications to Five Mortality Measures in the Hospital Inpatient Quality Reporting and Value-based Purchasing Programs.

++ Measuring Emergency Care Access and Timeliness in the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs—Request for Information.

++ Potential Future Use of the Adult Community-Onset Sepsis Standardized Mortality Ratio Measure in the Hospital Inpatient Quality Reporting Program—Request for Information.

- In section IX.C. of the preamble of this proposed rule, the Hospital Inpatient Quality Reporting Program.

- In section IX.D. of the preamble of this proposed rule, the PPS-Exempt Cancer Hospital Quality Reporting Program.

- In section IX.E. of the preamble of this proposed rule, the Long-Term Care Hospital Quality Reporting Program.

- In section IX.F. of the preamble of this proposed rule, the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs.

**B. Crosscutting Quality Program Proposals and Requests for Comment**

1. Proposed Adoption of the Advance Care Planning Electronic Clinical Quality Measure in the Hospital Inpatient Quality Reporting, PPS-Exempt Cancer Hospital Quality Reporting, and Medicare Promoting Interoperability Programs

**a. Background**

The 1990 Patient Self-Determination Act requires hospitals to inform patients of their rights regarding medical decisions and document the execution of an advance directive in medical records.<sup>157</sup> In the CY 2016 Medicare Physician Fee Schedule final rule (80 FR 70955 through 70959), we authorized Medicare payment to reimburse practitioners for time devoted

<sup>157</sup> Patient Self-Determination Act of 1990. 42 U.S. Code §§ 1395cc(f), 1396a(w).

to advance care planning services under specific procedure codes beginning in CY 2016.<sup>158</sup> Despite this, engagement in advance care planning remains low.<sup>159 160</sup> Among Medicare Fee-For-Service beneficiaries, the advance care planning procedure codes were billed for less than 6 percent of patients in the three years after their introduction,<sup>161</sup> and about 5 percent of practitioners billed them in 2021.<sup>162</sup>

Many patients assume that their caregivers know their preferences regarding their care, but caregivers incorrectly predict the patients' preferences one-third of the time.<sup>163</sup> Additionally, care preferences may change over time,<sup>164</sup> particularly if there are changes in an individual's health status or circumstances.<sup>165 166</sup> From the patient perspective, the benefits of documenting advance care planning can include increased autonomy, reduced unwanted and unnecessary treatments,

and reduced length and number of hospitalizations as well as allowing more time with family and loved ones.<sup>167</sup> A study among terminally ill Medicare beneficiaries also found that earlier advance care planning conversations were associated with less intensive care, including lower rates of in-hospital death, hospital admission, intensive care unit (ICU) admission, and emergency department (ED) visits.<sup>168</sup> These findings underscore the need for early, iterative conversations to keep care aligned with evolving patient goals and values, and for families and clinicians to have clear guidance in the event that patients are unable to convey their preferences.<sup>169 170</sup> Core elements of advance care planning include identifying a trusted health care proxy or surrogate decision-maker, clarifying care priorities for quality of life, and discussing specific treatments and interventions including resuscitation, intubation, ventilation, and ICU admission.<sup>171</sup> Inpatient care teams routinely manage high-stakes decisions and care transitions, making hospitalization an opportune moment to initiate or update advance care planning documentation and ensure updated directives are accessible to clinicians across subsequent care settings.

#### b. Overview of Measure

The Advance Care Planning electronic clinical quality measure (eCQM) calculates the proportion of adult patients with one or more inpatient hospitalizations during the measurement period who, by the time of hospital discharge for at least one encounter, have an advance care

planning document or documentation of an advance care planning discussion resulting in a documented decision in the patient's electronic health record (EHR). This eCQM is intended to promote timely advance care planning by encouraging communication between patients and providers to elicit and document the patient's care preferences and surrogate decision-makers, thereby supporting age-friendly and goal-concordant care. The promotion of patient-centered care and utilization of EHRs to support health information exchange are important priorities across our quality reporting programs. Standardized advance care planning documentation in an EHR furthers these priorities to keep care aligned with patients' stated preferences across the care continuum. The Advance Care Planning eCQM allows for automated extraction of patient-level data directly from the EHR. We refer readers to the Electronic Clinical Quality Improvement Resource Center (eCQI) for detailed eCQM measure specifications and implementation guidance for each reporting period: <https://ecqi.healthit.gov/eh-cah/ecqm-resources>.

#### c. Measure Calculation

The measure numerator includes all adult patients with one or more inpatient encounters during the measurement period who have an advance care planning document or documentation of an advance care planning discussion resulting in a documented decision in the patient's EHR by the time of hospital discharge during at least one of the inpatient encounters. At this time, the numerator comprises any one of the following: (1) advance care planning document as evidenced by the following types of documents: designated health care agent (health care proxy or medical power of attorney for health care),<sup>172</sup> advance directive (or living will), or a portable medical order (medical order for life sustaining treatment [MOLST] or physician order for life sustaining treatment [POLST] or do not resuscitate [DNR] orders);<sup>173</sup> or (2) documentation

<sup>172</sup> The designated health care agent accounts for the presence of a documented health care proxy or medical power of attorney that is either already established or identified and documented during the inpatient encounter. These forms allow a patient to identify a specific person who can make an advance care planning decision on the patient's behalf. States vary in the hierarchy of advance care planning decision-making by an undesignated proxy, and these state specifics are out of scope for the measure.

<sup>173</sup> Some state organizations may refer to a MOLST or POLST form by other terms such as:

Continued

<sup>158</sup> For additional information regarding the Advance Care Planning procedure codes, refer to the Fact Sheet available at: <https://www.cms.gov/files/document/mln-advanced-care-planning.pdf>.

<sup>159</sup> Gelfman LP, Barnes DE, Goldstein N, Volow AM, Shi Y, Li B, Sudore R. (2023). Quality and Satisfaction With Advance Care Planning Conversations Among English- and Spanish-Speaking Older Adults. *Journal of Palliative Medicine*, 26(10), 1380–1385. Available at: <https://doi.org/10.1089/jpm.2022.0565>.

<sup>160</sup> Sacks OA, Murphy M, O'Malley J, Birkmeyer N, Barnato AE. (2024). A Quality Improvement Initiative for Inpatient Advance Care Planning. *JAMA Health Forum*, 5(10):e243172. Available at: <https://doi.org/10.1001/jamahealthforum.2024.3172>.

<sup>161</sup> Weissman JS, Gazarian P, Reich A, Tjia J, Prigerson HG, Sturgeon D, Manful A. (2020). Recent Trends in the Use of Medicare Advance Care Planning Codes. *Journal of Palliative Medicine*, 23(12), 1568–1570. Available at: <https://doi.org/10.1089/jpm.2020.0437>.

<sup>162</sup> Wang N, Jiang C, Paulk E, Wang T, Hu X. (2025). Physician Billing for Advance Care Planning Among Medicare Fee-For-Service Beneficiaries, 2016–2021. *The Permanente Journal*, 29(3), 105–110. Available at: <https://doi.org/10.7812/TPP/24.177>.

<sup>163</sup> National Institute on Aging. (2022). Advance Care Planning: Advance Directives for Health Care. Available at: <https://www.nia.nih.gov/health/advance-care-planning/advance-care-planning-advance-directives-health-care>.

<sup>164</sup> Mastropolo R, Cernik C, Uno H, Fisher L, Xu L, Laurent CA, Cannizzaro N, Munneke J, Cooper RM, Lakin JR, Schwartz CM, Casperson M, Altschuler A, Kushi L, Chao CR, Wiener L, Mack JW. (2024). Evolution in Documented Goals of Care at End of Life for Adolescents and Younger Adults With Cancer. *JAMA Network Open*, 7(12), e2450489. Available at: <https://doi.org/10.1001/jamanetworkopen.2024.50489>.

<sup>165</sup> Shah MP, Wenger NS, Glaspy J, Hays RD, Sudore RL, Rahimi M, Gibbs L, Anand S, Tseng CH, Walling AM. (2025). Patient-reported discordance between care goals and treatment intent in advanced cancer. *Cancer*, 131(17), e35976. Available at: <https://doi.org/10.1002/cnrc.35976>.

<sup>166</sup> Young Y, Stone A, Perre T. (2022). Are Young Adults Ready to Complete Advance Directives? *American Journal of Hospice & Palliative Medicine*, 39(10), 1188–1193. Available at: <https://doi.org/10.1177/10499091211066494>.

<sup>167</sup> Goswami P. (2021). Advance Care Planning and End-Of-Life Communications: Practical Tips for Oncology Advanced Practitioners. *Journal of the advanced practitioner in oncology*, 12(1), 89–95. Available at: <https://doi.org/10.6004/jadpro.2021.12.1.7>.

<sup>168</sup> Weissman JS, Reich AJ, Prigerson HG, Gazarian P, Tjia J, Kim D, Rodgers P, Manful A. (2021). Association of Advance Care Planning Visits With Intensity of Health Care for Medicare Beneficiaries With Serious Illness at the End of Life. *JAMA Health Forum*, 2(7), e211829. Available at: <https://doi.org/10.1001/jamahealthforum.2021.1829>.

<sup>169</sup> Shah MP, Wenger NS, Glaspy J, Hays RD, Sudore RL, Rahimi M, Gibbs L, Anand S, Tseng CH, Walling AM. (2025). Patient-reported discordance between care goals and treatment intent in advanced cancer. *Cancer*, 131(17), e35976. Available at: <https://doi.org/10.1002/cnrc.35976>.

<sup>170</sup> National Institute on Aging. (2022). Advance Care Planning: Advance Directives for Health Care. Available at: <https://www.nia.nih.gov/health/advance-care-planning/advance-care-planning-advance-directives-health-care>.

<sup>171</sup> National Institute on Aging. (2022). Advance Care Planning: Advance Directives for Health Care. Available at: <https://www.nia.nih.gov/health/advance-care-planning/advance-care-planning-advance-directives-health-care>.



that an advance care planning discussion with a documented decision occurred during the measurement period.<sup>174</sup>

To be counted in the numerator, the advance care planning document must be available in the patient's EHR during any hospitalization in the measurement period. The measure does not require a date reflecting the document's origination or when it was last updated; however, we encourage hospitals to support their health care providers in discussing with the patient, or their surrogate, whether the document accurately reflects the patient's current preferences. In order to be counted as an advance care planning discussion leading to a decision, the documentation of the discussion with a decision must have a date in the EHR that occurs during an inpatient encounter in the measurement period. If a patient has multiple inpatient encounters during the measurement period, an advance care planning discussion with a decision occurring in any one of the inpatient encounters during the measurement period is counted toward the numerator. For a

detailed list of the EHR data elements that comprise the numerator of this proposed eCQM, please refer to the CMS QualityNet website, where a list is posted under both the Hospital Inpatient Quality Reporting Program<sup>175</sup> and PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program<sup>176</sup> sections during the comment period.

The denominator includes all patients aged 18 years and older at the start of the measurement period who are discharged from an inpatient hospitalization during the measurement period, which is a 12-month period that would run from January 1 through December 31 of each applicable calendar year.

There are no numerator or denominator exclusions.<sup>177</sup> The Advance Care Planning eCQM is calculated as a proportion by dividing the number of patients who meet the numerator criterion by the total number of eligible patients who meet the denominator criterion.

We note the PCH Quality Reporting Program currently uses another measure, Documentation of Goals of Care Discussions Among Cancer

Patients measure (88 FR 59222 through 59224), which has some similar aims; however, it only evaluates whether specific oncology patients at a reporting PCH had documentation related to prognosis, treatment, and goals for care. The Advance Care Planning eCQM focuses on documenting condition-agnostic medical instructions and surrogate decision-makers among all adult patients, which are intended to remain applicable across care settings.

Updated data element feasibility has been tested in two EHR systems, and measure score reliability has been tested in 43 hospitals across three health systems.<sup>178</sup> Testing was completed in hospitals representing a mix of urban and rural hospitals, hospital sizes, teaching statuses (for example, teaching vs. non-teaching), and trauma levels. Hospital-level performance rates are summarized in Table IX.B.1. As higher scores indicate better performance, the higher percentiles are hospitals with higher proportions of an advance care planning document or a documented advance care planning conversation with a recorded decision in the EHR.

**TABLE IX.B.1. HOSPITAL PERFORMANCE IN MEASURE TESTING FOR THE ADVANCE CARE PLANNING ECQM**

| Performance Percentile    | Measure Proportions |
|---------------------------|---------------------|
| 10 <sup>th</sup>          | 23.2%               |
| 50 <sup>th</sup> (Median) | 34.7%               |
| 90 <sup>th</sup>          | 60.5%               |

The wide range and variation of results indicate room for quality improvement and aligns with evidence in the literature that advance care planning remains low. Test results indicated high measure reliability and validity (including agreement between data exported from the EHR and manual review of the patient chart). For detailed information on the measure specifications, please refer to: <https://www.p4qm.org/prmr-measures/>

medical orders for scope of treatment (MOST), physician orders for scope of treatment (POST), clinical orders for life-sustaining treatment (COLST), or a transportable physician orders for patient preferences (TPOPP).

<sup>174</sup> Documentation that an advance care planning discussion with decision occurring during the measurement period includes a discussion with the patient or the surrogate. This allows discussion with a surrogate in instances where a patient is unable to participate (for example, incapacitated) without requiring prior discussion with the patient.

<sup>175</sup> Available at: <https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures>.

<sup>176</sup> Available at: <https://qualitynet.cms.gov/pch/pchqr/proposedmeasures>.

*muc2025-020*. During the Technical Expert Panel (TEP) convened by the measure developer, interested parties broadly supported the measure's validity and felt it provides meaningful information to make care decisions. For more details on the TEP discussion, we refer readers to the TEP Summary Report available at: <https://mmshub.cms.gov/sites/default/files/CORE-ACP-TEP3SummaryReport-092625.pdf>.

<sup>177</sup> There are no numerator or denominator exclusions as the eCQM is intended to encourage advance care planning among all adults, recognizing that serious illness or injury can occur at any time, regardless of age or baseline health. The numerator is designed to account for situations where a patient does not have capacity to engage in, declines, or defers advance care planning by crediting pre-existing advance care planning documents in the EHR and advance care planning discussions with documented decisions during an inpatient encounter (including those conducted with a surrogate when the patient did not have capacity and those where the patient preferred to not name a surrogate or provide an advance care plan).

d. Pre-Rulemaking Process and Measure Endorsements

(1) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement for details on the Pre-Rulemaking Measure Review process convened by the consensus-based entity (CBE), including the voting procedures used to reach consensus on measure recommendations.<sup>179</sup> <sup>180</sup> The

<sup>178</sup> Partnership for Quality Measurement. Advance Care Planning. Available at: <https://www.p4qm.org/prmr-measures/muc2025-020>.

<sup>179</sup> Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. Available at: <https://www.p4qm.org/prmr/about>.

<sup>180</sup> In 2025, the CBE updated the Pre-Rulemaking Measure Review voting process such that Recommendation Group members will vote to either "recommend" or "do not recommend" that a measure be added to the intended CMS program(s), thus, removing the "recommend with conditions" voting option. The threshold to reach consensus on a given measure continues to be a minimum of 75 percent agreement among members.

Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and

13, 2026, to review measures included by the Secretary on the publicly available “2025 Measures Under Consideration List,” including the Advance Care Planning eCQM.<sup>181</sup> Table IX.B.2. summarizes the voting results for this eCQM in the Hospital Inpatient Quality Reporting, PCH Quality

Reporting, and Medicare Promoting Interoperability Programs. For all three programs, the Recommendation Group reached consensus to recommend adoption of the Advance Care Planning eCQM within each program.<sup>182</sup>

**TABLE IX.B.2. PRE-RULEMAKING MEASURE REVIEW HOSPITAL RECOMMENDATION GROUP VOTING RESULTS FOR THE ADVANCE CARE PLANNING ECQM**

| Program                              | Voted to Recommend | Voted to Not Recommend | Consensus Reached | Recommendation Decision |
|--------------------------------------|--------------------|------------------------|-------------------|-------------------------|
| Hospital Inpatient Quality Reporting | 19 (90%)           | 2 (10%)                | Yes               | Recommend               |
| PCH Quality Reporting                | 20 (95%)           | 1 (5%)                 | Yes               | Recommend               |
| Medicare Promoting Interoperability  | 16 (76%)           | 5 (24%)                | Yes               | Recommend               |

Overall, the Pre-Rulemaking Measure Review Hospital Committee largely recognized the importance of advance care planning to improve communication and documentation of patient preferences and to promote patient-centered care. However, it raised concerns that the eCQM does not capture situations when patients decline or defer advance care planning and suggested inclusion of EHR codes that capture these instances. We understand the concerns of patients declining or deferring advance care planning discussions and include EHR codes for these situations. Specifically, hospitals can code for instances where a patient did not name a surrogate or provide an advance care plan; therefore, accommodating the situation where a conversation took place but no plan or proxy was named per the patient’s preference.

A few Recommendation Group members who voted to recommend adoption of the Advance Care Planning eCQM recommended adding a length of stay (LOS) requirement to ensure trust between the patient and provider and studying the measure among young adults.

We appreciate the members’ recommendations to add a length of stay requirement and to study it among young adults. We considered these recommendations and have determined that revision is not appropriate at this time as the goal of this measure is to establish advance care planning as a

normalized, routine part of care regardless of health status and age. For patients facing imminent death as well as those expected to recover quickly, advance care planning is a priority as circumstances can change quickly. However, we will continue to evaluate these topics as additional information, experience, or analysis develops.

A Recommendation Group member who voted not to recommend adoption of the eCQM for the Programs stated it would function as a check-the-box exercise rather than meaningful integration of patient preferences into care. This member noted that hospitals already ask whether a DNR order or advance directive is in place and that care teams rarely review these documents or integrate patients’ wishes into the care plan. The member stated that advance care planning should primarily occur with a primary care provider or a specialist managing the patient’s chronic conditions. We appreciate this feedback, and we wish to emphasize that we consider eliciting and documenting patients’ preferences for care and designation of surrogate decision-makers to be a fundamental element of providing high-quality, patient-centered, and goal-concordant care. While the eCQM assesses presence of EHR codes rather than the quality of underlying conversations, this documentation is critical for care teams to reliably locate and use advance care planning information when making clinical decisions. Furthermore,

hospitalization is a critical touchpoint to initiate advance care planning or to confirm and update existing information.

Additionally, a few Recommendation Group members who voted not to recommend adoption of the eCQM for the Medicare Promoting Interoperability Program indicated that they supported implementing and evaluating the eCQM in the Hospital Inpatient Quality Reporting Program before considering it for the Medicare Promoting Interoperability Program. Another member stated that the eCQM was not sufficiently defined for use in the Medicare Promoting Interoperability Program but did not provide additional detail regarding this concern in their vote rationale.

As the measure specifications proposed for the Medicare Promoting Interoperability Program are the same as those proposed for the Hospital Inpatient Quality Reporting and PCH Quality Reporting Programs, we believe they are sufficiently defined and appropriate for use across all three programs. The eCQM underwent extensive analysis and measure specifications development required for the endorsement process. Test results indicated high measure reliability and validity (including agreement between data exported from the EHR and manual review of the patient chart).<sup>183</sup> We also plan to maintain alignment of eCQM reporting requirements and the eCQM measure set between the Hospital

<sup>181</sup> Centers for Medicare & Medicaid Services. (December 2025). 2025 Measures Under Consideration List. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview>.

<sup>182</sup> Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary: Hospital Committee. Available at <https://p4qm.org/sites/default/files/2026-02/>

*PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf*.

<sup>183</sup> Partnership for Quality Measurement. MERIT Submission Form, Downloads, Advance Care Planning. Available at: <https://www.p4qm.org/prmr-measures/muc2025-020>.

Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program. If the eCQM is finalized for one or more programs, we would continue to conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences.

After taking these recommendations and concerns into consideration, we propose to adopt the Advance Care Planning eCQM in the Hospital Inpatient Quality Reporting Program, PCH Quality Reporting Program, and the Medicare Promoting Interoperability Program.

## (2) Measure Endorsements

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. We propose to adopt this measure into the Hospital Inpatient Quality Reporting Program and the PCH Quality Reporting Program despite the measure not being endorsed by the CBE. Section 1886(b)(3)(B)(viii)(IX)(aa) of the Act requires that each measure specified by the Secretary for use in the Hospital Inpatient Quality Reporting Program be endorsed by the entity with a contract under section 1890(a) of the Act, and section 1866(k)(3)(A) of the Act imposes the same requirement for measures specified for use in the PCH Quality Reporting Program. Sections 1886(b)(3)(B)(viii)(IX)(bb) and 1866(k)(3)(B) of the Act state, however, that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exceptions in sections 1886(b)(3)(B)(viii)(IX)(bb) and 1866(k)(3)(B) of the Act apply.

## e. Data Sources, Submission, and Public Reporting

The proposed Advance Care Planning eCQM is specified in a standard electronic format, utilizing data extracted from EHRs, which would minimize errors due to manual

abstraction of data.<sup>184</sup> In addition, by utilizing data in the EHR, it would allow updated directives to potentially be accessible to clinicians across subsequent care settings. The measure is designed to be calculated by a hospital's or PCH's certified health IT using patient-level data and then submitted by the hospital or PCH to CMS.

Testing was performed to confirm the feasibility of the measure and data elements with manual review of EHR data against chart-abstracted data. Testing demonstrated that all critical data elements were reliably and consistently captured in the EHR.<sup>185</sup> Additionally, data element validity testing revealed a high level of agreement between EHR data and chart review (92 percent and above) for all data elements except Advance Directive; however, all fifteen patients with electronically identified "Advance Directive" documents that were not present upon chart review (that is, they did not have an advance directive document in their chart) had another advance care planning document in their chart that fulfilled the numerator criteria.<sup>186</sup> Finally, the measure showed high reliability, with a mean of 0.9987 and standard deviation of 0.0012.<sup>187</sup> These results indicate that the measure is reliable and feasible to implement.

In section IX.D.5. of this proposed rule, we are proposing to introduce eCQM reporting and submission requirements to the PCH Quality Reporting Program, under which PCHs would be required to use certified health IT to report and submit eCQMs. PCHs are specialized acute care settings that provide intensive inpatient oncology services. As the measure was successfully tested in a variety of inpatient hospital types and is specified using data elements expected to be available in certified EHR technology, we believe that the high level of feasibility, validity, and reliability observed in a blend of acute care hospitals is reasonably applicable to

PCHs despite their specialty focus on cancer patients. Further, we would monitor implementation and measure performance in PCHs and consider refinements if setting-specific issues arise.

For the Hospital Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program, we propose to adopt the Advance Care Planning eCQM as part of the eCQM measure set beginning with the CY 2028 reporting period/FY 2030 payment determination. A hospital can self-select eCQMs to report from the eCQM measure set to meet the eCQM reporting requirement. We refer readers to sections IX.C.8.c. and IX.F.9. respectively of this proposed rule for a discussion of proposed eCQM form, manner, and timing of data submission and reporting requirements for these two programs. For the PCH Quality Reporting Program, we propose to adopt the Advance Care Planning eCQM beginning with the CY 2028 reporting period/FY 2030 program year. We refer readers to section IX.D.5. of this proposed rule for a discussion of proposed eCQM form, manner, and timing of data submission and reporting requirements for the PCH Quality Reporting Program.

If adoption of the Advance Care Planning eCQM is finalized, we propose to publicly report data as soon as it is feasible on CMS websites such as the Compare tool on Medicare.gov (<https://www.medicare.gov/care-compare/>) and the CMS Provider Data Catalog or their successor websites after a 30-day preview period.

We invite public comment on our proposals.

## 2. Proposed Adoption and Modifications to Five Mortality Measures in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs

### a. Background

In the CY 2007 OPPS/ASC final rule (71 FR 68205 through 68206), we began adopting condition-specific and procedure-specific mortality measures into the Hospital Inpatient Quality Reporting Program to more fully reflect patient outcomes following hospitalization. Beginning with the FY 2014 program year, we adopted mortality measures into the Hospital Value-Based Purchasing Program, under the Clinical Outcomes domain, specifically:

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction

<sup>184</sup> Centers for Medicare & Medicaid Services. (2023). Electronic Clinical Quality Measures (eCQMs) Specification, Testing, Standards, Tools, and Community. Available at: <https://mmshub.cms.gov/sites/default/files/eCQM-Specifications-Testing-Standards-Tools-Community.pdf>.

<sup>185</sup> Partnership for Quality Measurement. Meaningfulness Tab, Advance Care Planning. Available at: <https://www.p4qm.org/prmr-measures/muc2025-020>.

<sup>186</sup> Partnership for Quality Measurement. MERIT Submission Form, Downloads, Advance Care Planning. Available at: <https://www.p4qm.org/prmr-measures/muc2025-020>.

<sup>187</sup> Partnership for Quality Measurement. Meaningfulness Tab, Advance Care Planning. Available at: <https://www.p4qm.org/prmr-measures/muc2025-020>.

Hospitalization (MORT-30-AMI) measure (76 FR 26495 through 26511);

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (MORT-30-HF) measure (76 FR 26495 through 26511);

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT-30-PN) measure (adopted at 76 FR 26495 through 26511; modified at 81 FR 56994 through 56996);

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT-30-COPD) measure (80 FR 49557 through 49558); and

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG)

Surgery (MORT-30-CABG) measure (81 FR 56996 through 56998).

For more details on these five mortality measures, we refer readers to the condition-specific and the procedure-specific mortality measures updates and specifications reports available at: <https://qualitynet.cms.gov/inpatient/measures/mortality/methodology>.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41556 through 41558), after adopting these measures into a pay-for-performance program, the Hospital Value-Based Purchasing Program, we removed them from the Hospital Inpatient Quality Reporting Program, a pay-for-reporting program, under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We subsequently removed these measures from the Hospital Inpatient Quality

Reporting Program, while maintaining them in the Hospital Value-Based Purchasing Program, as a part of our ongoing effort to move the programs forward in the least burdensome manner possible, while maintaining parsimonious sets of quality measures and continuing to incentivize improvement in the quality of care provided to patients. These five mortality measures continue to provide meaningful information for patients on the quality and value of care provided at a hospital and continue to be included in the calculation of incentive payment adjustments for the Hospital Value-Based Purchasing Program. Table IX.B.3. summarizes our previously finalized policies for these five mortality measures in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs.

**TABLE IX.B.3. SUMMARY OF FIVE MORTALITY MEASURES INITIAL AND FINAL PAYMENT DETERMINATION OR PROGRAM YEARS IN THE HOSPITAL INPATIENT QUALITY REPORTING AND VALUE-BASED PURCHASING PROGRAMS**

| Measure Name | First Payment Determination in Hospital Inpatient Quality Reporting Program | First Program Year in Hospital Value-Based Purchasing Program | Last Payment Determination in Hospital Inpatient Quality Reporting Program |
|--------------|-----------------------------------------------------------------------------|---------------------------------------------------------------|----------------------------------------------------------------------------|
| MORT-30-AMI  | FY 2008 (71 FR 68205 through 68206)                                         | FY 2014 (76 FR 26495 through 26511)                           | FY 2020 (83 FR 41556 through 41558)                                        |
| MORT-30-HF   | FY 2008 (71 FR 68205 through 68206)                                         | FY 2014 (76 FR 26495 through 26511)                           | FY 2020 (83 FR 41556 through 41558)                                        |
| MORT-30-PN   | FY 2009 (72 FR 66875 through 66877)                                         | FY 2014 (76 FR 26495 through 26511)                           | FY 2021 (83 FR 41556 through 41558)                                        |
| MORT-30-COPD | FY 2016 (78 FR 50792 through 50794)                                         | FY 2021 (80 FR 49557 through 49558)                           | FY 2021 (83 FR 41556 through 41558)                                        |
| MORT-30-CABG | FY 2016 (78 FR 50798 through 50802)                                         | FY 2022 (81 FR 56996 through 56998)                           | FY 2022 (83 FR 41556 through 41558)                                        |

In this proposed rule, we propose to adopt the modified versions of the MORT-30-AMI, MORT-30-HF, MORT-30-PN, MORT-30-COPD, and the MORT-30-CABG measures in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination. We would also modify these measures in the Hospital Value-Based Purchasing Program and remove them from the Hospital Inpatient Quality Reporting Program beginning with the FY 2032 payment determination. When these five mortality measures were previously adopted into the Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Programs, they only included Medicare Fee-For-Service beneficiaries in the measure cohorts.

Since the initial adoption of these measures, the proportion of Medicare Advantage beneficiaries has increased from 35 percent of the Medicare population to approximately 50 percent.<sup>188</sup> If finalized as proposed, the modified mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-PN, MORT-30-COPD, and MORT-30-CABG) will have been publicly reported in the Hospital Inpatient Quality Reporting Program for at least 1 year in accordance with the statutory and regulatory requirements of section 1886(o)(2)(C)(i) of the Act and 42 CFR 412.164(b), before adoption into the

<sup>188</sup> Centers for Medicare & Medicaid Services. (2025). Medicare Enrollment Dashboard. Available at: <https://data.cms.gov/tools/medicare-enrollment-dashboard>.

Hospital Value-Based Purchasing Program.

#### b. Overview of Proposed Updates

We are proposing two substantive modifications to these five mortality measures: (1) expand the measure inclusion criteria to include Medicare Advantage beneficiaries; and (2) shorten the performance period from 3 to 2 years. Inclusion of Medicare Advantage beneficiaries expands quality measurement of patient outcomes following hospitalization across all Medicare beneficiaries, enhances the reliability of measure scores, leads to more hospitals receiving results, and increases the chance of identifying meaningful differences in quality for some low-volume hospitals. Based on

our analysis that included Medicare Advantage beneficiaries in addition to the Medicare Fee-For-Service measure cohort, we found that the measures could achieve a satisfactory level of reliability with a 2-year reporting period.<sup>189</sup> The mean reliability for each

of the modified mortality measures exceeded the CBE established minimum threshold of 0.6.<sup>190</sup> We therefore propose to shorten the reporting period from 3 to 2 years for the modified mortality measures. Table IX.B.4. summarizes our reliability estimates for

the five modified mortality measures using a 2 year reporting period (CY 2022–CY 2023) and inclusion of Medicare Advantage beneficiaries:

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**TABLE IX.B.4. MORTALITY MEASURES RELIABILITY ESTIMATES USING A 2-YEAR REPORTING PERIOD**

| Measure Title | Mean (SD)     | Min-Max     | 25 <sup>th</sup> Percentile | 50 <sup>th</sup> Percentile | 75 <sup>th</sup> Percentile |
|---------------|---------------|-------------|-----------------------------|-----------------------------|-----------------------------|
| MORT-30-AMI   | 0.772 (0.009) | 0.739-0.788 | 0.765                       | 0.771                       | 0.779                       |
| MORT-30-HF    | 0.712 (0.009) | 0.686-0.730 | 0.705                       | 0.712                       | 0.719                       |
| MORT-30-PN    | 0.900 (0.065) | 0.264-0.911 | 0.905                       | 0.907                       | 0.909                       |
| MORT-30-COPD  | 0.771 (0.009) | 0.729-0.786 | 0.766                       | 0.771                       | 0.778                       |
| MORT-30-CABG  | 0.726 (0.024) | 0.633-0.768 | 0.715                       | 0.729                       | 0.744                       |

Table IX.B.5. summarizes the proposed new performance periods for the Hospital Inpatient Quality Reporting Program and Hospital Value-Based

Purchasing Program, beginning with the FY 2028 payment determination. We refer readers to section V.L.3. for more details on the baseline and performance

periods in the Hospital Value-Based Purchasing Program for the FY 2032 program year and subsequent years.

**TABLE IX.B.5. SUMMARY OF PROPOSED PERFORMANCE PERIODS FOR FIVE MODIFIED MORTALITY MEASURES IN THE HOSPITAL INPATIENT QUALITY REPORTING AND VALUE-BASED PURCHASING PROGRAMS**

| Measure Title                                                           | Proposed Initial Performance Period and Payment Determination in the Hospital Inpatient Quality Reporting Program |         | Proposed Final Performance Period and Payment Determination in the Hospital Inpatient Quality Reporting Program |         | Proposed Initial Performance Period and Program Year in the Hospital Value-Based Purchasing Program |         |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|---------|-----------------------------------------------------------------------------------------------------------------|---------|-----------------------------------------------------------------------------------------------------|---------|
|                                                                         |                                                                                                                   |         |                                                                                                                 |         |                                                                                                     |         |
| MORT-30-AMI<br>MORT-30-HF<br>MORT-30-PN<br>MORT-30-COPD<br>MORT-30-CABG | July 1, 2024 – June 30, 2026                                                                                      | FY 2028 | July 1, 2027 – June 30, 2029                                                                                    | FY 2031 | July 1, 2028 – June 30, 2030                                                                        | FY 2032 |

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For more details on the measure refinement methodology and results for these measures, we refer readers to the condition-specific and procedure-specific mortality measures updates and specifications reports available at: <https://qualitynet.cms.gov/inpatient/measures/mortality/methodology>.

**c. Measure Calculation**

The outcomes for the modified mortality measures, MORT-30-AMI, MORT-30-HF, MORT-30-PN, MORT-30-COPD, and MORT-30-CABG, would

continue to measure 30-day, all-cause mortality.

The measures are calculated by first determining the ratio of the number of “predicted” deaths (the adjusted number of deaths at a specific hospital based on its patient population) to the number of “expected” deaths (the number of deaths if an average quality hospital treated the same patients) for each hospital and then multiplies the ratio by the national observed mortality rate. The ratio of predicted to expected deaths is greater than one for a hospital that has more deaths than would be

expected for an average hospital with similar cases and less than one if the hospital has fewer deaths than would be expected for an average hospital with similar cases. This allows for a comparison of a particular hospital’s performance to an average hospital’s performance with the same case mix. This approach is analogous to a ratio of an “observed” or “crude” rate to an “expected” or risk adjusted rate used in other similar types of statistical analyses.

<sup>189</sup> Partnership for Quality Measurement. (December 2025). 2025 Pre-Rulemaking Measure Review Preliminary Assessment. Available at: <https://p4qm.org/prmr-measures/muc2025-036> (MORT-30-AMI); <https://p4qm.org/prmr-measures/>

[muc2025-037](https://p4qm.org/prmr-measures/muc2025-037) (MORT-30-HF); <https://p4qm.org/prmr-measures/muc2025-044> (MORT-30-PN); <https://p4qm.org/prmr-measures/muc2025-040> (MORT-30-COPD); and <https://p4qm.org/prmr-measures/muc2025-046> (MORT-30-CABG).

<sup>190</sup> For more details on reliability guidance, we refer readers to the Reliability Guidance for the Endorsement and Maintenance of Clinical Quality Measures Document available at: <https://p4qm.org/em/resources>.

## (1) Numerator

The numerator for this measure is 30-day, all-cause mortality. We define mortality as death from any cause within 30 days of the start of the index admission, including in-hospital death.

## (2) Denominator

The cohort includes admissions for patients that meet all of the following inclusion criteria:

- Discharged from the hospital with a principal discharge diagnosis of AMI, HF, COPD, pneumonia, or a qualifying CABG procedure;
- Enrolled in Medicare Fee-For-Service Part A and Part B or Medicare Advantage for the first 12 months prior to the date of admission and enrolled in Part A or Medicare Advantage during the index admission;<sup>191</sup>
- Aged 65 or older; and
- Not transferred from another acute care facility.

If a patient has more than one eligible AMI, HF, COPD, pneumonia, or CABG procedure hospitalization during the reporting period, then we randomly select one admission, or eligible procedure,<sup>192</sup> per year for inclusion in the measure cohort.<sup>193</sup>

For more information regarding measure specifications, including denominator exclusion criteria, we refer readers to condition-specific and procedure-specific mortality measures methodology reports at: <https://qualitynet.cms.gov/inpatient/measures/mortality/methodology>.

## d. Pre-Rulemaking Process and Measure Endorsements

## (1) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement for details on the Pre-Rulemaking Measure Review

process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.<sup>194</sup> <sup>195</sup> The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available “2025 Measures Under Consideration List,” including the MORT-30-AMI, MORT-30-HF, MORT-30-PN, MORT-30-COPD, and the MORT-30-CABG measures.<sup>196</sup> Table IX.B.6. summarizes the voting results for measure recommendations for these measures in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs.

**TABLE IX.B.6. PRE-RULEMAKING MEASURE REVIEW HOSPITAL RECOMMENDATION GROUP VOTING RESULTS**

| Measure                                             | MUC ID      | Voted to Recommend | Voted to Not Recommend | Consensus Reached | Recommendation Decision                                      |
|-----------------------------------------------------|-------------|--------------------|------------------------|-------------------|--------------------------------------------------------------|
| <b>Hospital Inpatient Quality Reporting Program</b> |             |                    |                        |                   |                                                              |
| MORT-30-AMI                                         | MUC2025-036 | 17 (81%)           | 4 (19%)                | Yes               | Recommend                                                    |
| MORT-30-HF                                          | MUC2025-037 | 17 (81%)           | 4 (19%)                | Yes               | Recommend                                                    |
| MORT-30-PN                                          | MUC2025-044 | 16 (80%)           | 4 (20%)                | Yes               | Recommend                                                    |
| MORT-30-COPD                                        | MUC2025-040 | 16 (80%)           | 4 (20%)                | Yes               | Recommend                                                    |
| MORT-30-CABG                                        | MUC2025-046 | 17 (85%)           | 3 (15%)                | Yes               | Recommend                                                    |
| <b>Hospital Value-based Purchasing Program</b>      |             |                    |                        |                   |                                                              |
| MORT-30-AMI                                         | MUC2025-036 | 16 (76%)           | 5 (24%)                | Yes               | Recommend                                                    |
| MORT-30-HF                                          | MUC2025-037 | 15 (75%)           | 5 (25%)                | Yes               | Recommend                                                    |
| MORT-30-PN                                          | MUC2025-044 | 15 (75%)           | 5 (25%)                | Yes               | Recommend                                                    |
| MORT-30-COPD                                        | MUC2025-040 | 15 (75%)           | 5 (25%)                | Yes               | Recommend                                                    |
| MORT-30-CABG                                        | MUC2025-046 | 15 (71%)           | 6 (29%)                | No                | Majority of the Recommendation Group expressed some support. |

<sup>191</sup> This requirement is not applicable to Veterans Health Administration (VHA) beneficiaries hospitalized in VHA hospitals, who are eligible for inclusion in the cohort regardless of their Medicare enrollment status. VHA beneficiaries hospitalized in non-VHA hospitals must be concurrently enrolled in Medicare Fee-For-Service Part A or Medicare Advantage at the time of the index admission to be eligible for cohort inclusion.

<sup>192</sup> A qualifying isolated CABG surgery is defined as a procedure performed without the following concomitant valve or other major cardiac, vascular, or thoracic procedures: valve procedures; atrial and/or ventricular septal defects; congenital

anomalies; other open cardiac procedures; heart transplants; aorta or other non-cardiac arterial bypass procedures; head, neck, intracranial vascular procedures; or other chest and thoracic procedure.

<sup>193</sup> Centers for Medicare & Medicaid Services. (December 2025). 2025 Measures Under Consideration List. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview>.

<sup>194</sup> Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. Available at: <https://www.p4qm.org/prmr/about>.

<sup>195</sup> We note the Pre-Rulemaking Measure Review voting process was updated in 2025. We refer readers to the corresponding footnote in section IX.B.1.d.(1). of this proposed rule for more details on the updated Pre-Rulemaking Measure Review voting process.

<sup>196</sup> Centers for Medicare & Medicaid Services. (December 2025). 2025 Measures Under Consideration List. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview>.

For the Hospital Inpatient Quality Reporting Program, the Recommendation Group reached consensus and recommended the five modified mortality measures for adoption into the program. For the Hospital Value-Based Purchasing Program, the Recommendation Group reached consensus for four of the five modified mortality measures, the MORT-30-AMI, MORT-30-HF, MORT-30-PN, and MORT-30-COPD measures, and thus, recommended these measures for adoption into the Hospital Value-Based Purchasing Program. The Recommendation Group did not reach consensus to recommend the MORT-30-CABG measure for the Hospital Value-Based Purchasing Program, although the majority of the Recommendation Group did express some support.<sup>197</sup>

The Recommendation Group largely supported the addition of Medicare Advantage beneficiaries to the measures' cohorts and underscored the importance of enhancing transparency and facilitating meaningful comparisons and high-quality care by including this

population. The Recommendation Group also generally agreed that shortening the reporting period from 3 to 2 years would lead to more actionable insights. Some members recommended further analysis to ensure the effects of including Medicare Advantage beneficiaries to the measures' cohorts are understood. Some members that did not vote to recommend these measures emphasized the need to understand the impacts of including Medicare Advantage beneficiaries in hospital performance in the Hospital Value-Based Purchasing Program prior to implementation. We appreciate the member's recommendation to ensure the impacts of including Medicare Advantage beneficiaries in the measure's cohorts is understood and we wish to emphasize that, based on our analysis, the variation between the two cohorts did not vary significantly for mortality rates, and the reliability estimate for the modified measures showed satisfactory results.<sup>198</sup> Therefore, the inclusion of Medicare Advantage beneficiaries does not raise concerns regarding potential

variation between the Fee-For-Service and Medicare Advantage cohorts for these measures, or unintended consequences on hospital performance. We note that as a part of routine measure maintenance, we conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences. Table IX.B.7. shows the results for observed 30-day mortality rates for the Medicare Fee-For-Service, Medicare Advantage, and combined cohorts, as well as the difference between the Medicare Fee-For-Service and Medicare Advantage cohorts for the proposed modified mortality measures. Further, based on our analysis, we found that the mean reliability estimates for the modified mortality measures, using two years of data (CY 2022–2023), and the updated cohort, all exceeded the CBE established minimum threshold of 0.6.<sup>199</sup> We refer readers to Table IX.B.4., in section IX.B.2.b., for a description of our reliability estimates for the modified mortality measures, which includes estimates with the updated cohorts.

TABLE IX.B.7. MORTALITY RATE FOR MEDICARE FEE-FOR-SERVICE, MEDICARE ADVANTAGE FOR PROPOSED MODIFIED MORTALITY MEASURES, CY 2022

| Measure Name | Medicare Advantage and Fee-For-Service Combined Cohort | Fee-For-Service Only Cohort | Medicare Advantage Only Cohort | Difference Between Fee-For-Service and Medicare Advantage Cohorts |
|--------------|--------------------------------------------------------|-----------------------------|--------------------------------|-------------------------------------------------------------------|
| MORT-30-AMI  | 12.3%                                                  | 12.5%                       | 12.1%                          | 0.4%                                                              |
| MORT-30-HF   | 11.5%                                                  | 12.2%                       | 10.7%                          | 1.4%                                                              |
| MORT-30-PN   | 16.8%                                                  | 17.3%                       | 16.2%                          | 1.1%                                                              |
| MORT-30-COPD | 8.9%                                                   | 9.4%                        | 8.4%                           | 1.0%                                                              |
| MORT-30-CABG | 2.8%                                                   | 2.7%                        | 2.9%                           | -0.2%                                                             |

Some Recommendation Group members who recommended adopting the modified mortality measures for the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs also provided considerations for strengthening the measures. Many of these recommendations included considerations for improving the risk adjustment model. Specifically, some members recommended adjusting for socioeconomic status in the risk model for all mortality measures. Some

members that voted to recommend this measure suggested considering including the cause of death in the risk model to improve accuracy. Other members voted not to recommend these measures for the two programs, citing that additional evaluation of the updated risk model is needed.

Regarding the recommendation to add socioeconomic status factors to the risk adjustment model, we note that our analysis found that including these factors showed minimal impact to

measure performance. This analysis also found that including these factors could result in negative impacts to vulnerable populations by lowering the expected mortality for these groups, and we decided to exclude these factors from our risk adjustment model. Regarding the recommendation to include the cause of death to improve the risk model, we thank the Recommendation Group members for this recommendation and will consider this in our routine measure maintenance.

<sup>197</sup> Partnership for Quality Measurement. (February 2026). PRMR 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

<sup>198</sup> Partnership for Quality Measurement. (March 2024). 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report. Available at: <https://p4qm.org/prmr-measures/muc2025-036>.

<sup>199</sup> For more details on reliability guidance, we refer readers to the Reliability Guidance for the Endorsement and Maintenance of Clinical Quality Measures Document available at: <https://p4qm.org/em/resources>.

Regarding the recommendation for additional evaluation of the updated risk model, we wish to emphasize that we have conducted extensive evaluation and based on our analysis using the updated risk adjustment methodology, the ability of the updated risk adjustment model to account for condition-specific or procedure-specific severity improved significantly. We refer readers to section IX.B.2.f. for a detailed discussion of our updates to our risk adjustment methodology and summary of our analysis comparing the results of the modified measures using the two risk adjustment methodologies.

Recommendation Group members emphasized that the modified measures should be re-submitted for endorsement prior to implementation as a rationale for not voting to recommend this measure for the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs. Other key reasons cited for not recommending these modified mortality measures included recommending a phased implementation approach for the measure modifications, as well as confidential reporting to ensure a clear understanding of measure impacts. Some members expressed concerns about whether small or rural hospitals would be able to meet volume thresholds for these measures with the reduced reporting period.

Regarding members' recommendation to re-submit the modified measures for endorsement, these measures are currently endorsed by the CBE and have been re-submitted for endorsement review with these measure modifications for the Spring 2026 cycle. In response to the members that recommended a phased implementation of the measures modifications as well as

confidential reports, we note that we intend to provide hospitals with measure performance data with the expanded patient cohort based on data collected while the modified versions of these measures are in use in the Hospital Inpatient Quality Reporting Program via annual confidential hospital-specific reports beginning with the FY 2028 program year, as well as via annual Provider Participation Summary Reports under the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year. Further, we propose the modified mortality measures take effect for the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year, which will provide time and data to monitor for any unintended consequences. In addition, the FY 2032 Hospital Value-Based Purchasing Program performance standards for this measure would be published at least 60 days prior to the beginning of each applicable performance period as required by section 1886(o)(3)(C) of the Act. Regarding the concern about whether small or rural hospitals would be unduly burdened by the shortening of the reporting period from 3 to 2 years, we wish to note that the decrease in cohort size is largely offset with the addition of Medicare Advantage beneficiaries to measure cohorts; thus, we do not anticipate small or rural hospitals to be unduly burdened by this update.

Specifically for the MORT-30-CABG measure, one member cited the potential for unintended consequences for hospitals to refuse care for patients with complex co-morbidities as their rationale for not recommending this measure for either the Hospital Inpatient Quality Reporting Program or the

Hospital Value-Based Purchasing Program. We appreciate the Recommendation Group member's concern about unintended consequences. Based on our analysis with the current risk adjustment methodology, which includes risk adjustment for patient frailty, we do not anticipate hospitals to be unfairly penalized for treating patients who may be more complex. We refer readers to Table IX.B.4., in section IX.B.2.b., and Table IX.B.9., in section IX.B.2.f., for more details on our analysis of measure reliability and the risk adjustment methodology. Further, as a part of routine measure maintenance, we conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences.

After taking these recommendations and concerns into consideration, we propose to adopt the modified mortality measures in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination and subsequently modify the mortality measures in Hospital Value-Based Purchasing Program beginning with the FY 2032 program year.

#### (2) Measures Endorsements

We refer readers to the Partnership for Quality Measurement website for details on the measure Endorsement and Maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. Table IX.B.8. summarizes the most recent endorsement status and the next planned Endorsement and Maintenance review for five modified mortality measures:

**TABLE IX.B.8. FIVE MORTALITY MEASURES ENDORSEMENT STATUS**

| Measure Title | CBE# | Most Recent Endorsement | Next Endorsement and Maintenance Review |
|---------------|------|-------------------------|-----------------------------------------|
| MORT-30-AMI   | 0230 | Fall 2020               | Spring 2026                             |
| MORT-30-HF    | 0229 | Fall 2020               | Spring 2026                             |
| MORT-30-PN    | 0468 | Fall 2020               | Spring 2026                             |
| MORT-30-COPD  | 1893 | Fall 2020               | Spring 2026                             |
| MORT-30-CABG  | 2558 | Fall 2022               | Spring 2026                             |

#### e. Data Source, Submission and Public Reporting

These measures would be calculated using administrative data from Medicare Fee-For-Service claims or hospital-submitted Medicare Advantage claims, and Medicare Advantage Organization-submitted encounter data. This data is routinely generated by hospitals and

submitted to CMS for all Medicare beneficiaries, which includes Medicare Advantage and Medicare Fee-For-Service beneficiaries. Therefore, a hospital would not be required to report any additional data for this measure. Enrollment status would be obtained from the Medicare Enrollment Database which contains beneficiary

demographic, benefit/coverage, and vital status information.

The proposed modified mortality measures would be calculated and publicly reported on an annual basis using a rolling 24 months of prior data for the measurement period, consistent with the approach currently used for the MORT-30-STK measure, the COMP-



HIP–KNEE measure, and the Thirty-day Risk-Standardized Death Rate Among Surgical Inpatients with Complications measure currently reported in the Hospital Inpatient Quality Reporting Program (90 FR 36997 through 37002, 90 FR 37002 through 37008, and 89 FR 69545 through 69552). We would then publicly report the measures results on the Compare tool, currently available at: <https://www.medicare.gov/care-compare/>, beginning in July 2027 or as soon as feasible for the Hospital Inpatient Quality Reporting Program, which would enable us to post data for at least 1 year before adopting the modifications into the Hospital Value-Based Purchasing Program, as required by section 1886(o)(2)(C)(i) of the Act. For the Hospital Value-Based Purchasing Program, we also propose that the performance standards calculation methodology for the modified mortality measures would be the same as that which we currently use for the mortality measures. The performance standards for the modified measures for FY 2032 are not yet available.

We invite public comment on our proposals to adopt five modified mortality measures, MORT–30–AMI,

MORT–30–HF, MORT–30–PN, MORT–30–COPD, and the MORT–30–CABG, into the Hospital Inpatient Quality Reporting Program from the FY 2028 payment determination through the FY 2031 payment determination, and subsequently remove these measures from the Hospital Inpatient Quality Reporting Program beginning with the FY 2032 payment determination, as a step towards substantively modifying them in the Hospital Value-Based Purchasing Program. We also invite public comment on our proposal to modify these five mortality measures in the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year, contingent on our adoption of these changes in the Hospital Inpatient Quality Reporting Program.

f. Technical Updates

We are also notifying the public of technical updates to the risk adjustment methodology for the five modified mortality measures’ proposed for adoption in the Hospital Inpatient Quality Reporting Program, beginning with the FY 2028 payment determination, and for modification in the Hospital Value-Based Purchasing

Program, beginning with the FY 2032 program year, to use individual International Classification of Diseases (ICD–10) codes instead of hierarchical condition categories (HCC) to improve the measure’s risk adjustment methodology. The risk adjustment strategy currently in use involves grouping ICD–10 diagnosis codes from CMS’s HCC system into clinically relevant categories (76 FR 26495 through 26511, 80 FR 49557 through 49558, and 81 FR 56994 through 56996). We then evaluate the HCCs for statistical association with the measures’ outcomes. To better leverage the data and analytical advances since the measure was initially developed, we created a new approach to use individual ICD–10 codes for risk adjustment. Research has indicated that using individual ICD–10 codes in place of HCCs could significantly improve the model performance of the mortality measures. With this new approach, the ability of the risk adjustment model to account for condition-specific or procedure-specific severity was significantly better. See Table IX.B.9. for a summary of improvements to the risk adjustment models’ performance for the five modified mortality measures.<sup>200</sup>

TABLE IX.B.9. RISK ADJUSTMENT MODEL PERFORMANCE COMPARISON USING CALENDAR YEAR 2022 DATA

| Measure Title | Fee-For-Service-only cohort with HCC-based Risk Variables |                                             | Fee-For-Service and Medicare Advantage cohort with ICD-10-based Risk Variables |                                             |
|---------------|-----------------------------------------------------------|---------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------------|
|               | C-statistic (predictive ability %)                        | Signal-to-Noise Reliability Median (Q1, Q3) | C-statistic (predictive ability %)                                             | Signal-to-Noise Reliability Median (Q1, Q3) |
| MORT–30–AMI   | 0.79 (1.2 – 41.6)                                         | 0.51 (0.4, 0.6)                             | 0.86 (1.0 – 63.3)                                                              | 0.73 (0.6, 0.8)                             |
| MORT–30–HF    | 0.69 (2.5 – 27.3)                                         | 0.67 (0.5, 0.8)                             | 0.83 (1.1 – 51.4)                                                              | 0.9 (0.8, 0.9)                              |
| MORT–30–PN    | 0.73 (2.8 – 41.3)                                         | 0.63 (0.5, 0.7)                             | 0.85 (1.2 – 69.2)                                                              | 0.89 (0.8, 0.9)                             |
| MORT–30–COPD  | 0.74 (1.2 – 26.0)                                         | 0.54 (0.5, 0.6)                             | 0.85 (0.7 – 45.9)                                                              | 0.74 (0.6, 0.8)                             |
| MORT–30–CABG  | 0.79 (0.2 – 11.9)                                         | 0.82 (0.8, 0.9)                             | 0.85 (0.4 – 16.2)                                                              | 0.88 (0.8, 0.9)                             |

3. Measuring Emergency Care Access and Timeliness in the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs—Request for Information

a. Background

Occupancy and boarding rates in EDs continue to worsen and exceed pre-

pandemic levels. ED boarding, defined as holding a patient in the ED after the patient is admitted or placed into observation status at a hospital, is an outcome of misaligned incentives to deploy care delivery resources in a particular way,<sup>201</sup> often resulting in shortages of inpatient beds and staff. ED boarding contributes to ED crowding,

leading to safety risks for patients and stressful working conditions for healthcare personnel.<sup>202 203 204</sup> A recent report from the Agency for Healthcare Research and Quality (AHRQ) characterized patient ED boarding as a growing public health crisis and engaged interested parties to address the

<sup>200</sup> Partnership for Quality Measurement. (March 2024). 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report. Available at: <https://p4qm.org/prmr-measures/muc2025-036>.

<sup>201</sup> Michael, S.S., Bruna, S., Sessums, L.L. (2025). Building a public-private partnership to confront the emergency department boarding crisis, *Health Affairs Scholar*, 3(4). Available at: <https://doi.org/10.1093/haschl/qxaf014>.

<sup>202</sup> Morley, C., Unwin, M., Peterson, G.M., Stankovich, J., Kinsman, L. (2018). Emergency department crowding: A systematic review of causes, consequences and solutions. *PLoS One*, 13(8):e0203316. Available at: <https://doi.org/10.1371/journal.pone.0203316>.

<sup>203</sup> Moore, C. & Heckmann, R. (2025). Hospital Boarding In The ED: Federal, State, And Other Approaches. *Health Affairs Forefront*. Available at: <https://www.healthaffairs.org/content/forefront/>

*hospital-boarding-ed-federal-state-and-other-approaches*.

<sup>204</sup> Rizk, D. (2025). *Systemic solutions to emergency department boarding: The hospitalist's perspective*. *Health Affairs Scholar*, 3(9). Available at: <https://academic.oup.com/healthaffairsscholar/article/3/9/qxaf168/8241101>.

strain on the United States healthcare system.<sup>205</sup>

Recent studies indicate that delays in the timeliness of ED care are associated with patient harm.<sup>206–207</sup> Long ED wait times are also one of the most cited reasons for patients leaving an ED without being evaluated by a clinician.<sup>208</sup> Increased ED LOS is also a strong predictor of poor timeliness of care and is significantly impacted by ED boarding. One study of several EDs within a single health system found that for every patient boarded, the median ED LOS for all admitted patients increased by at least 12 minutes.<sup>209</sup> Other evidence indicates that prolonged boarding is concentrated among older adults and is associated with downstream impacts that extend beyond the ED encounter.<sup>210</sup> Furthermore, ED boarding and crowding have been associated with poor patient outcomes, such as increased mortality,<sup>211</sup> delays in needed care,<sup>212</sup> and negative patient and staff experiences.<sup>213–214</sup> For instance,

evidence shows that ED crowding can harm patients with sepsis by delaying administration of lifesaving intravenous (IV) fluids and antibiotics.<sup>216</sup> Additionally, there may be additional operational and financial burdens associated with ED boarding, underscoring its relevance to inpatient capacity management and hospital performance.<sup>217</sup>

Studies have documented a significantly higher likelihood of boarding when hospital occupancy rates exceed 85 percent.<sup>218–219</sup> These dynamics became more pronounced during the COVID-19 public health emergency, when national hospital occupancy increased by 11 percentage points, while staffed hospital beds declined by roughly 16 percent.<sup>220</sup> Data such as these have supported the argument made by a number of emergency medicine clinicians and researchers that ED efficiency and patient throughput are closely tied to a broad collection of hospital-wide

operational processes beyond those just occurring in the ED, including but not limited to inpatient bed management, staffing and procedure scheduling, discharge planning and post-acute care access, and diagnostic and consult turnaround.<sup>221</sup>

In line with this perspective, evidence suggests that hospitals which perform better on metrics related to ED boarding are more likely to adopt cross-departmental initiatives (for example, ED, radiology, laboratory services, hospitalist, surgery, housekeeping, nursing) to alleviate crowding.<sup>222</sup> Hence, hospital administrators, individual departments, and associated staff can collectively participate in a variety of processes and interventions that can contribute to lower levels of boarding in the ED. Actions that make discharges earlier, more predictable, and daily (for example, identifying “next-day discharges” during afternoon rounds, using expected date of discharge documented on admission when possible, performing early morning discharge rounds, enabling weekend and holiday discharges, pre-completing discharge paperwork and medication reconciliation) can free beds in preparation of future peaks in ED utilization.<sup>223–224</sup> “Smoothing” the surgical schedule to ensure a steady, predictable demand for inpatient beds throughout the week can eliminate artificial peaks and valleys in bed demand that could otherwise contribute to boarding.<sup>225</sup> Employing real-time monitoring and other predictive capabilities within health information technology systems can also identify new efficiencies in triaging and staffing that can result in better rates of bed

<sup>205</sup> Agency for Healthcare Research and Quality. (2025). Technical Report: AHRQ Summit To Address Emergency Department Boarding. Available at: <https://www.ahrq.gov/sites/default/files/wysiwyg/topics/ed-boarding-summit-report.pdf>.

<sup>206</sup> Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine*, 35(7), 953–960. Available at: <https://doi.org/10.1016/j.ajem.2017.01.061>.

<sup>207</sup> Laam L.A., Wary A.A., Strony R.S., Fitzpatrick M.H., & Kraus C.K. (2021). Quantifying the impact of patient boarding on emergency department length of stay: All admitted patients are negatively affected by boarding. *Journal of American College Emergency Physicians*, 2(2):e12401. Available at: <https://doi.org/10.1002/emp2.12401>.

<sup>208</sup> Janke, A.T., Melnick, E.R., & Venkatesh, A.K. (2022). Monthly Rates of Patients Who Left Before Accessing Care in US Emergency Departments, 2017–2021. *JAMA*, 5(9), e2233708. Available at: <https://doi.org/10.1001/jamanetworkopen.2022.33708>.

<sup>209</sup> Laam L.A., Wary A.A., Strony R.S., Fitzpatrick M.H., & Kraus C.K. (2021). Quantifying the impact of patient boarding on emergency department length of stay: All admitted patients are negatively affected by boarding. *Journal of American College Emergency Physicians*, 2(2):e12401. Available at: <https://doi.org/10.1002/emp2.12401>.

<sup>210</sup> Sifnugel, N., et al. (2025). An analysis of boarding trends in older adults in the United States. *Health Affairs Scholar*, 3(10). Available at: <https://doi.org/10.1093/haschl/qxaf187>.

<sup>211</sup> Hsuan, C., Segel, J.E., Hsia, R.Y., Wang, Y., & Rogowski, J. (2023). Association of emergency department crowding with inpatient outcomes. *Health Services Research*, 58(4), 828–843. Available at: <https://doi.org/10.1111/1475-6773.14076>.

<sup>212</sup> Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine*, 35(7), 953–960. Available at: <https://doi.org/10.1016/j.ajem.2017.01.061>.

<sup>213</sup> Reznick, M.A., Larkin, C.M., Scheulen, J.J., Harbertson, C.A., & Michael, S.S. (2021).

Operational factors associated with emergency department patient satisfaction: Analysis of the Academy of Administrators of Emergency Medicine/Association of Academic Chairs of Emergency Medicine national survey. *Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine*, 28(7), 753–760. Available at: <https://doi.org/10.1111/acem.14278>.

<sup>214</sup> Loke, D.E., Green, K.A., Wessling, E.G., Stulpin, E.T., & Fant, A.L. (2023). Clinicians’ Insights on Emergency Department Boarding: An Explanatory Mixed Methods Study Evaluating Patient Care and Clinician Well-Being. *Joint Commission Journal on Quality and Patient Safety*, 49(12), 663–670. Available at: <https://doi.org/10.1016/j.jcjq.2023.06.017>.

<sup>215</sup> Norton, V., Schreyer, K.E., Kuhn, D. (2025). Workforce impact of emergency department boarding. *Health Affairs Scholar*, 3(8). Available at: <https://doi.org/10.1093/haschl/qxaf134>.

<sup>216</sup> Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine*, 35(7), 953–960. Available at: <https://doi.org/10.1016/j.ajem.2017.01.061>.

<sup>217</sup> Canellas, M.M., et al. (2024). Measurement of cost of boarding in the emergency department. *Annals of Emergency Medicine*. Available at: <https://doi.org/10.1016/j.annemergmed.2024.04.012>.

<sup>218</sup> Kelen, G. D., Wolfe, R., D’Onofrio, G., Mills, A. M., Diercks, D., Stern, S. A., . . . & Sokolove, P. E. (2021). Emergency department crowding: the canary in the health care system. *NEJM Catalyst Innovations in Care Delivery*, 2(5). Available at: <https://catalyst.nejm.org/doi/abs/10.1056/CAT.21.0217>.

<sup>219</sup> Janke, A. T., Melnick, E. R., & Venkatesh, A. K. (2022). Hospital occupancy and emergency department boarding during the COVID-19 pandemic. *JAMA Network Open*, 5(9), e2233964–e2233964. Available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC9526134/>.

<sup>220</sup> Leuchter, R.K., Delarmente, B.A., Vangala, S., Tsugawa, Y., Sarkisian, C.A. (2025). Health care staffing shortages and potential national hospital bed shortage. *JAMA Netw Open*, 8(2):e2460645. Available at: <https://doi.org/10.1001/jamanetworkopen.2024.60645>.

<sup>221</sup> Rizk, D. (2025). Systemic solutions to emergency department boarding: The hospitalist’s perspective. *Health Affairs Scholar*, 3(9). Available at: <https://academic.oup.com/healthaffairsscholar/article/3/9/qxaf168/8241101>.

<sup>222</sup> Chang, A. M., Cohen, D. J., Lin, A., Augustine, J., Handel, D. A., Howell, E., . . . & Sun, B. C. (2018). Hospital strategies for reducing emergency department crowding: a mixed-methods study. *Annals of emergency medicine*, 71(4), 497–505. Available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC5828915/>.

<sup>223</sup> Bechir, G., & Bechir, A. (2025). Start With the End: Early Hospital Discharge Planning as a Day-One Priority. *Cureus*, 17(6). Available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC12308768/>.

<sup>224</sup> The Hospitalist. “Tips for Improving Early Discharge Rates.” Published May 29, 2016. Available at: <https://www.the-hospitalist.org/hospitalist/article/121668/patient-safety/tips-improving-early-discharge-rates/>.

<sup>225</sup> Rathlev, N. K., Chessare, J., & Litvak, E. (2018). Redesigning the surgical schedule to enhance productivity in the operating room. *J Emerg Med Trauma Surg Care*, 5, 023. Available at: <https://www.heraldopenaccess.us/openaccess/redesigning-the-surgical-schedule-to-enhance-productivity-in-the-operating-room>.

turnover.<sup>226 227</sup> Other examples of interventions that have been considered to address this issue include care transitions, point-of-care testing, observation units, streaming, short-stay units, strengthening triage and ED teams, creating new care zones, use of capacity protocols, and other administrative or organizational improvements.<sup>228 229 230 231</sup>

Notably, the breadth and variation in these strategies makes it clear that no single intervention will solve the ED boarding crisis, particularly when considering the effectiveness of these actions is likely to vary across patient populations, health status and comorbidities, and case-mix. As such, it is important for throughput and patient flow to be viewed as a shared responsibility within the healthcare delivery system. To that end, quality measures should reflect and promote a culture of accountability.

#### b. Overview of Measure

The Emergency Care Access & Timeliness eCQM is currently specified for the hospital setting and calculates the proportion of four outcome metrics that quantify access to and timeliness of care in a hospital ED setting against specified thresholds, including: (1) patient wait time—1 hour; (2) whether the patient left the ED without being evaluated; (3) patient boarding time in the ED (as defined by a Decision to Admit (order) to ED departure for admitted patients)—4 hours; and (4)

patient ED LOS (time from ED arrival to ED physical departure, as defined by the ED departure timestamp)—8 hours.

Measure testing for the Emergency Care Access & Timeliness eCQM was conducted by the measure developer across 32 hospital-based EDs, representing a diverse mix of geographic regions, rurality, hospital size, teaching status, trauma level, and EHR vendors, demonstrating that the measure is reliable, valid, and feasible for all required data elements.<sup>232</sup> Measure testing results showed a wide range in overall scores, and across all strata, indicating variation in performance and implying room for quality improvement.<sup>233</sup>

#### (1) Numerator

The measure numerator includes any ED encounter in the denominator where the patient experiences any one of the following: (1) the patient waited longer than 1 hour after arrival to the ED to be placed in a treatment room or dedicated treatment area that allows for audiovisual privacy during history-taking and physical examination; (2) the patient left the ED without being evaluated; (3) the patient boarded in the ED for longer than 4 hours; and (4) the patient had an ED LOS of longer than 8 hours.<sup>234</sup> An encounter is considered part of the numerator if it includes any one of the four numerator events, with events not being mutually exclusive and each contributing only once to the numerator. ED encounters with ED observation stays<sup>235</sup> are excluded from components (3) and (4) but are included in the denominator. Patients who have a “decision to admit” after an ED observation stay remain excluded from criteria (3) calculations.<sup>236</sup>

These four outcomes were selected based on published literature

demonstrating that each numerator component is associated with patient harm, as well as input from clinical experts including ED experts and statistical and methodological experts and a TEP that was convened by the measure developer.<sup>237</sup> A Patient and Family Engagement Work Group provided feedback on experiences with emergency care, noting long wait times to be seen by a provider, long wait times to be transferred, and gaps in the discharge processes.

The numerator thresholds were developed according to evidence and consensus-based clinical guidelines for ED time thresholds, including guidelines developed by The Joint Commission (TJC), the American College of Emergency Physicians (ACEP), and the Emergency Department Benchmarking Alliance as well as input from a TEP, literature reviews, and environmental scans. For example, the 4-hour threshold for numerator component (3), boarding time, was developed according to recommendations from TJC and ACEP.<sup>238 239</sup> This threshold reflects delays that are influenced by inpatient bed availability, hospital capacity, and admission processes.

#### (2) Denominator

The measure denominator includes all ED encounters associated with patients of all ages, for all-payers, during a 12-month period of performance. Patients can have multiple encounters during a period of performance, and each encounter is eligible to contribute to the calculation of the measure.<sup>240</sup>

#### (3) Measure Calculation

The measure score is first calculated at the individual ED level as the proportion of ED encounters where any one of the four outcomes occurred. Raw measure scores are then standardized by ED case volume using z-scores. The z-score, or standard score, indicates how many standard deviations a data point

<sup>226</sup> Sinsical, A. (2025). 171 Streamlining Inpatient Discharge Processes to Reduce Emergency Department Boarding. *Annals of Emergency Medicine*, 86(3), S73–S74. Available at: [https://www.annemergmed.com/article/S0196-0644\(25\)00566-9/fulltext](https://www.annemergmed.com/article/S0196-0644(25)00566-9/fulltext).

<sup>227</sup> Boland, R. (2025). “4 strategies to reduce ED overcrowding.” *Healthcare Financial Management Association*. Available at: <https://www.hfma.org/operations-management/4-strategies-to-reduce-ed-overcrowding/>.

<sup>228</sup> Austin, E.E., Blakely, B., Tufanaru, C. et al. (2020). Strategies to measure and improve emergency department performance: a scoping review. *Scand J Trauma Resusc Emerg Med*, 28, 55. Available at: <https://doi.org/10.1186/s13049-020-00749-2>.

<sup>229</sup> De Freitas, L., Goodacre, S., O'Hara, R., Thokala, P., Hariharan, S. (2018). Interventions to improve patient flow in emergency departments: an umbrella review. *Emerg Med J*, 35(10):626–637. Available at: <https://doi.org/10.1136/emered-2017-207263>.

<sup>230</sup> Burns TA, Kaufman B, Stone RM. (2022). An EMS Transport Destination Officer is Associated with Reductions in Simultaneous Emergency Department Arrivals. *Prehosp Emerg Care*. Available at: <https://doi.org/10.1080/10903127.2022.2107126>.

<sup>231</sup> Bittencourt, R.J., Stevanato, A.M., Bragança, C.T.N.M., Gottens, L.B.D., O'Dwyer, G. (2020). Interventions in overcrowding of emergency departments: an overview of systematic reviews. *Rev Saude Publica*. 54:66. Available at: <http://doi.org/10.11606/s1518-8787.2020054002342>.

<sup>232</sup> Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at: <https://www.p4qm.org/measures/4625e>.

<sup>233</sup> Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at: <https://www.p4qm.org/measures/4625e>.

<sup>234</sup> For proposed measure specifications, we refer readers to the eCQI Resource Center at <https://ecqi.healthit.gov/ecqm/hosp-outpt/2027/cms1244v1>, or the CMS QualityNet Hospital Outpatient Quality Reporting Program website at: <https://qualitynet.cms.gov/outpatient>.

<sup>235</sup> ED observations stays are defined as an observation encounter where the patient remains physically in an area under control of the ED and under the care of an ED clinician inclusive of observation in a hospital bed. Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at: <https://p4qm.org/measures/4625e>.

<sup>236</sup> Specific codes required to calculate the numerator are outlined in the value set data dictionary and eCQM package (Quality Data Model—QDM output). Please refer to the “Measure Calculation” Section for information at: <https://p4qm.org/measures/4625e>.

<sup>237</sup> Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at: <https://p4qm.org/measures/4625e>.

<sup>238</sup> The Joint Commission. (2012). Approved: Standards revisions addressing patient flow through the emergency department. Joint Commission perspectives. *Joint Commission on Accreditation of Healthcare Organizations*, 32(7), 1–5.

<sup>239</sup> American College of Emergency Physicians. (2024). Emergency Department Boarding and Crowding. Available at: <https://www.acep.org/administration/crowding-boarding>.

<sup>240</sup> For proposed measure specifications, we refer readers to the eCQI Resource Center at <https://ecqi.healthit.gov/ecqm/hosp-outpt/2027/cms1244v1>, or the CMS QualityNet Hospital Outpatient Quality Reporting Program website at <https://qualitynet.cms.gov/outpatient>.

is from the mean of a normal distribution. It is calculated by subtracting the mean from a data point, then dividing the result by the standard deviation. For the Emergency Care Access & Timeliness eCQM, a volume-adjusted z-score shows how an ED's performance compares to the average for similar-volume EDs, addressing differences in patient population in hospital outpatient departments (HOPD) and ensuring fair "like to like" comparisons between EDs of similar size. ED volume strata are defined in volume bands of 20,000 ED visits, and each ED is assigned to only one volume stratum. For CMS Certification Numbers (CCNs) with more than one ED, volume-adjusted z-scores are then combined as a weighted average for that CCN.<sup>241</sup>

The results of the Emergency Care Access & Timeliness eCQM are stratified into four groups, two by age (18 years and older, and under 18 years) and two by mental health diagnoses (with, and without).<sup>242</sup> Testing results during the measure development process indicates that the stratification of results by age and mental health diagnosis, as well as standardization of measure performance scores by volume, was sufficient to account for differences between HOPDs; however, we are seeking feedback on whether additional stratification or risk adjustment would be appropriate if the measure were considered for inclusion in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs.

We refer readers to the CY 2026 OPPS/ASC final rule, where the Emergency Care Access & Timeliness eCQM was adopted into the Hospital Outpatient Quality Reporting<sup>243</sup> and Rural Emergency Hospital (REH) Quality Reporting<sup>244</sup> Programs (90 FR 53925 through 53934; 90 FR 53945 through 53951). Further information and resources are available at the CMS QualityNet Hospital Outpatient Quality

Reporting Program website at <https://qualitynet.cms.gov/outpatient>, which also takes readers to the electronic specifications available at the eCQI Resource Center: <https://ecqi.healthit.gov/ecqm/hosp-outpt/2027/cms1244v1>.

#### c. Request for Comment on Potential Future Use in the Hospital Inpatient Quality Reporting and the Hospital Value-Based Purchasing Programs

We are considering how to best measure care access and timeliness among hospitals participating in its quality reporting and value-based purchasing programs. We recognize that this issue is not specific to one particular setting (that is, inpatient or outpatient), and that a higher-level approach may instead be needed. However, as currently designed, CMS's quality reporting programs are divided to separately monitor inpatient and outpatient settings. If proposed for future rulemaking, we could consider adopting the existing outpatient measure into the Hospital Inpatient Quality Reporting Program as currently specified, or we could make adjustments to tailor it more specifically for inpatient use. Such enhancements could include modifying specific numerator components or the overall denominator to be more applicable for the inpatient setting. However, this more targeted approach to inpatient quality measurement may be at odds with aligning access and timeliness at a systems-level as noted above.

We invite public comment on the potential use of the Emergency Care Access & Timeliness eCQM into the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs, in addition to the following questions:

- What are some of the key barriers and challenges faced by inpatient providers in supporting process changes that improve bed availability and reduce ED boarding?
- What are the best practices for providers within inpatient departments to actively engage with colleagues in other departments, as well as other settings that impact bed availability (for example, post-acute care facilities)? What barriers do providers face, especially rural providers, in establishing protocols for bi-directional communication?
- Are there any elements of this measure that are not applicable (for example, numerator components, denominator, exclusions, etc.) to inpatient care, or for which an inpatient hospital should not be held accountable, which would warrant removal or modification if the measure is proposed

in the Hospital Inpatient Quality Reporting Program?

++ For example, numerator components (1), (2), and (4) of the measure can occur for care provided entirely outside of an inpatient setting. This may lead to concerns that hospital inpatient processes are being evaluated based on the care and outcomes of patients who are not admitted during their stay.

++ On the other hand, as discussed above, ED boarding resulting from processes within the inpatient department impacts the throughput of *all ED patients*, which is reflected in numerator components (1), (2) and (4). Therefore, there are concerns that limiting the inpatient Emergency Care Access & Timeliness eCQM to those admitted or boarded may be insufficient to truly address access and timeliness issues.

- Given the overlap in patient cohort with the measure recently adopted for the Hospital Outpatient Quality Reporting Program, do stakeholders have concerns related to duplication of encounters in quality measures? Given the shared responsibility across units within the hospital, is it beneficial for the cohort (or a subset of the cohort) to be tracked across similar measures in both programs?

++ For example, we could consider developing separate measures for each program, where a version for use in inpatient quality reporting tracks access and timeliness amongst patients that were admitted during their stay, while an outpatient quality reporting measures version tracks those not admitted.

- Should CMS consider including this measure in the Hospital Value-Based Purchasing Program? If so, would it be beneficial to keep the current measure specifications as is, particularly as these programs may be better suited to capture broader, system-wide processes?

- Are there any potential unintended consequences CMS should be aware of related to introducing this measure into the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs?

- Are there other measure development/re-specification ideas or opportunities CMS should consider for how inpatient departments can address ED boarding and better measure patient outcomes, such as harm from delays to inpatient care?

<sup>241</sup> For proposed measure specifications, we refer readers to the CMS QualityNet Hospital Outpatient Quality Reporting Program website at <https://qualitynet.cms.gov/outpatient>.

<sup>242</sup> The principal diagnosis (first listed diagnosis at ED discharge) will be used to define strata inclusion. For this measure's purpose, mental health diagnoses do not include substance use disorder diagnoses. Mental health refers to mental health diagnoses, life stressors and crises, and stress-related physical symptoms.

<sup>243</sup> Available at: <https://www.federalregister.gov/d/2025-20907/p-3744>.

<sup>244</sup> Available at: <https://www.federalregister.gov/d/2025-20907/p-3956>. Notably, the specifications for several components in the REH Quality Reporting Program measure differ slightly from the Outpatient Quality Reporting specifications to reflect the fact that REHs do not have inpatient beds. The version of the measure being considered for inpatient reporting matches the Hospital Outpatient Quality Reporting specifications.

#### 4. Potential Future Use of the Adult Community-Onset Sepsis Standardized Mortality Ratio Measure in the Hospital Inpatient Quality Reporting Program—Request for Information

##### a. Background

Sepsis, or septicemia, is a life-threatening condition that results from the body's dysregulated response to infection and is a leading cause of mortality, hospitalization, and readmission in the United States.<sup>245</sup> It is the most frequent principal diagnosis among non-maternal, non-neonatal inpatients, with over 2.2 million hospitalizations reported in 2018.<sup>246</sup> Of the 1.7 million adults diagnosed with sepsis annually, approximately 20 percent die.<sup>247 248 249 250</sup>

Accurate tracking of sepsis incidence and outcomes can be challenging due to the lack of a definitive diagnostic test and wide variation in diagnosis and coding practices.<sup>251</sup> There are limitations to using claims data only, for example reporting delays and incomplete data for non-Medicare/Medicaid patients. Increased screening and coding for sepsis have led to more cases being identified, often inflating

case counts and lowering reported mortality rates.<sup>252</sup> A measure assessing the community-onset sepsis standardized mortality ratio is essential for producing timely, consistent, and clinically meaningful comparisons across hospitals.<sup>253</sup>

For the past several years, we have been working together with the CDC's National Healthcare Safety Network (NHSN) team to advance CMS's digital strategy through the use of digital quality measures (dQMs).<sup>254</sup> Through this collaboration, we have been exploring leveraging CDC's NHSNLink application programming interface (API) that would allow hospitals to exchange data and report digital quality measures to NHSN in a hands-free, fully automated manner, using the Fast Healthcare Interoperability Resources® (FHIR®) <sup>255</sup> standard for exchanging healthcare information electronically between information systems.<sup>256</sup> FHIR is a foundational, standards-based specification developed for secure and scalable electronic health information exchange. Using FHIR, data are represented based on nationally recognized standards across EHR vendors, facilities, and agencies. Through CDC's NHSNLink API, EHR data can be pulled from a facility, making real-time patient level, risk-adjusted surveillance feasible, while at the same time, it can also provide the data needed to calculate hospital quality measures for CMS quality programs, thus significantly reducing reporting burden for facilities. This enables different systems, such as EHRs and applications, to exchange information in a consistent, structured, and reusable format. CMS has already integrated the FHIR standard, and signaled the use of FHIR, in some of our interoperability requirements in our quality reporting modernization. CDC has implementation guides that describe the CDC NHSN's approach to digital data

and the technical specifications for reporting to NHSN. We refer readers to these resources for additional detail on the electronic reporting of NHSN digital quality measures: <https://hl7.org/fhir/us/nhsn-dqm/> and <https://www.cdc.gov/nhsn/fhirportal/dqm/ig/>. CDC is currently partnering with 19 hospitals and health systems across the United States who are working to pilot, implement, and validate NHSN dQMs. This network of hospitals will be the foundation for advancing new healthcare data exchange approaches like FHIR® and will provide valuable insights and lessons learned for implementing FHIR-based dQMs that can be shared with all United States hospitals as they build their FHIR capabilities.

CMS and CDC are collaborating on the development of several FHIR-based dQMs which may be adopted into CMS hospital quality programs in the coming years. Of these, we have identified the Adult Community-Onset Sepsis Standardized Mortality Ratio measure as a high priority due to high Sepsis mortality and morbidity. This measure was reviewed in the 2025 Pre-Rulemaking Measure Review process and is currently being tested as a pilot with NHSN partner hospitals (more information available at: <https://www.cdc.gov/nhsn/nhsncolab/index.html>).<sup>257</sup> These partners are submitting EHR FHIR data to NHSN as well as data from claims.

##### b. Overview of Measure

The Adult Community-Onset Sepsis Standardized Mortality Ratio measure provides hospitals with a nationally benchmarked metric of community-onset sepsis mortality outcomes, which can be used to measure their progress on improving the care of patients with sepsis. The measure uses data from the EHR in combination with claims data to provide robust risk-adjustment. All data elements are in defined fields in electronic sources and align with United States Core Data for Interoperability (USCDI) <sup>258</sup> and USCDI+ Quality <sup>259</sup> standards.

<sup>257</sup> Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

<sup>258</sup> Assistant Secretary for Technology Policy. United States Core Data for Interoperability (USCDI). Available at: <https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi>.

<sup>259</sup> Assistant Secretary for Technology Policy. USCDI+. Available at: <https://www.healthit.gov/topic/interoperability/uscdi-plus>.

<sup>245</sup> An Assessment of Sepsis in the United States and its Burden on Hospital Care. Rockville, MD: Agency for Healthcare Research and Quality; 2024. AHRQ Pub No. 24–0087. Available at: <https://hcup-us.ahrq.gov/reports/SepsisUSBurdenHospitalCare.pdf>.

<sup>246</sup> McDermott KW, Roemer M. (2021). Most Frequent Principal Diagnoses for Inpatient Stays in U.S. Hospitals, 2018. Healthcare Cost and Utilization Project (HCUP) Statistical Brief #277. Available at: <https://pubmed.ncbi.nlm.nih.gov/34428003/>.

<sup>247</sup> Centers for Disease Control and Prevention. About Sepsis. August 2025. Available at: <https://www.cdc.gov/sepsis/about/index.html>.

<sup>248</sup> U.S. Department of Health and Human Services. Agency for Healthcare Research and Quality. Report to Congress: An Assessment of Sepsis in the United States and its Burden on Hospital Care. 2024. Available at: [https://www.ahrq.gov/sites/default/files/publications/2/files/sepsis-report-to-congress\\_0.pdf](https://www.ahrq.gov/sites/default/files/publications/2/files/sepsis-report-to-congress_0.pdf).

<sup>249</sup> Page B, Klompas M, Chan C, Filbin MR, Dutta S, McEvoy DS, Clark R, Leibowitz M, Rhee C. (2021). Surveillance for healthcare-associated infections: hospital-onset adult sepsis events versus current reportable conditions. *Clin Infect Dis*, 73(6):1013–1019. Available at: <https://doi.org/10.1093/cid/ciab217>.

<sup>250</sup> Rhee C, Dantes R, Epstein L, Murphy DJ, Seymour CW, Iwashyna TJ, Kadri SS, Angus DC, Danner RL, Fiore AE, Jernigan JA, Martin GS, Septimus E, Warren DK, Karcz A, Chan C, Menchaca JT, Wang R, Gruber S, Klompas M; CDC Prevention Epicenter Program. (2017). Incidence and Trends of Sepsis in US Hospitals Using Clinical vs Claims Data, 2009–2014. *JAMA*, 318(13):1241–1249. Available at: <https://doi.org/10.1001/jama.2017.13836>.

<sup>251</sup> Rhee C, Kadri SS, Danner RL, Suffredini AF, Massaro AF, Kitch BT, Lee G, Klompas M. (2016). Diagnosing sepsis is subjective and highly variable: a survey of intensivists using case vignettes. *Crit Care*, 20,89. Available at: <https://doi.org/10.1186/s13054-016-1266-9>.

<sup>252</sup> Epstein L, Dantes R, Magill S, Fiore A. Varying estimates of sepsis mortality using death certificates and administrative codes—United States, 1999–2014. *MMWR Morb Mortal Wkly Rep*, 65(12), 342–345. Available at: <https://doi.org/10.15585/mmwr.mm6513a2>.

<sup>253</sup> Prescott HC, Heath M, Jayaprakash N, Dantes RB, Rhee C, Posa PJ, Flanders SA. (2025). Concordance of 30-Day Mortality and In-Hospital Mortality or Hospice Discharge After Sepsis. *JAMA*, 333(19), 1724–1726. Available at: <https://doi.org/10.1001/jama.2025.2526>.

<sup>254</sup> Centers for Disease Control and Prevention. NHSN Digital Quality Measures (dQMs). Available at: <https://www.cdc.gov/nhsn/fhirportal/>.

<sup>255</sup> FHIR® is the registered trademark of Health Level Seven International (HL7), and its use does not constitute endorsement by HL7.

<sup>256</sup> Centers for Disease Control and Prevention. NHSN Digital Quality Measures (dQMs). Available at: <https://www.cdc.gov/nhsn/fhirportal/>.

Empiric validity of the measure was tested by comparing hospital-level adult community-onset sepsis standardized mortality ratios (SMRs) to hospital-level process measures that are typically considered to reflect best practices for sepsis care in the first 3–6 hours (Severe Sepsis and Septic Shock Management Bundle [SEP–1]), Hospital 30-day, All-cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (pneumonia mortality), and the CMS Overall Hospital Star Rating. SMRs correlated with pneumonia mortality ( $p=0.27$ ,  $p<0.001$ ) and quality star ratings ( $p=-0.29$ ,  $p=0.001$ ). The results support the rationale for the Adult Community-Onset Sepsis Standardized Mortality Ratio measure that encourages hospitals to focus on the full breadth of sepsis care, from presentation through discharge, and foster innovation in identifying additional measures that meaningfully impact sepsis outcomes. The CDC calculated signal-to-noise reliability across 433,065 persons from 265 hospitals and reported a median reliability of 0.921.

#### (1) Measure Description

The measure assesses the annual risk-adjusted standardized mortality ratio (SMR) of adult inpatients with community-onset sepsis who died during their hospitalization or were discharged to hospice. The SMR is reported annually and is calculated by dividing the number of observed community-onset sepsis deaths by the number of predicted community-onset sepsis deaths.

#### (2) Numerator

The measure numerator is the number of annually observed adults with community-onset sepsis who died during hospitalization or were

discharged to hospice. The following are excluded from the numerator:

- Patients <18 years of age
- Length of hospitalization >120 days
- Patients with prior enrollment in hospice
- Patients that transferred to another acute care hospital

#### (3) Denominator

The measure denominator is the number of annually predicted adults with community-onset sepsis who died during hospitalization or were discharged to hospice.

#### (4) Measure Calculation

Hospital-level Standardized Mortality Ratio = (observed adult community-onset sepsis in-hospital mortality & discharge to hospice)/(predicted community-onset sepsis in-hospital mortality & discharge to hospice).

#### (5) Risk-Adjustment

This measure utilizes a risk-adjustment model incorporating baseline patient characteristics (age, sex), comorbidities, and detailed clinical data (including vital signs, laboratory values, positive blood cultures and COVID-19 tests, body mass index, and infection source per ICD-10 codes).

We refer readers to the NHSN digital Quality Measure Resource Center at <https://www.cdc.gov/nhsn/fhirportal/dqm/ach-dQMs.html> for more details on the measure specifications.

#### (6) Data Sources

Data are from EHRs that would be submitted via the FHIR-based NHSNLink API and augmented by claims data (specifically, ICD-10 codes) for specific components of the sepsis definition, certain exclusions, and part

of the risk adjustment. Hospitals' claims data could be submitted directly to NHSN by uploading .csv files or through a third party vendor on a hospital's behalf and would be similar in process to how facilities currently report claims data for the NHSN Surgical Site Infection measures.

#### c. Pre-Rulemaking Process and Measure Endorsement

##### (1) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement for details on the Pre-Rulemaking Measure Review process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.<sup>28 29</sup> The Pre Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available “2025 Measures Under Consideration List,” including the Adult Community-Onset Sepsis Standardized Mortality Ratio measure.<sup>260</sup> Table IX.B.10. summarizes the voting results for this measure in the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs. The Recommendation Group reached consensus to recommend adoption of the Adult Community-Onset Sepsis Standardized Mortality Ratio measure in the Hospital Inpatient Quality Reporting Program but did not reach consensus on the use of the measure in the Hospital Value-Based Purchasing Program.<sup>261</sup>

**TABLE IX.B.10. PRE-RULEMAKING MEASURE REVIEW HOSPITAL RECOMMENDATION GROUP VOTING RESULTS FOR THE ADULT COMMUNITY-ONSET SEPSIS STANDARDIZED MORTALITY RATIO MEASURE**

| Program                                 | Voted to Recommend | Voted to Not Recommend | Consensus Reached | Recommendation Decision                                      |
|-----------------------------------------|--------------------|------------------------|-------------------|--------------------------------------------------------------|
| Hospital Inpatient Quality Reporting    | 17 (81%)           | 4 (19%)                | Yes               | Recommend                                                    |
| Hospital Value-Based Purchasing Program | 12 (57%)           | 9 (43%)                | No                | Majority of the Recommendation Group expressed some support. |

<sup>260</sup> Centers for Medicare & Medicaid Services. (December 2025). 2025 Measures Under Consideration List. Available at: [https://mmshub.cms.gov/measure-lifecycle/measure-](https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview)

[implementation/pre-rulemaking/lists-and-reports/overview](https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview).

<sup>261</sup> Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final

Meeting Summary. Available at: <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

## (2) Measure Endorsement

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69458 through 69459) for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. Adult Community-Onset Sepsis Standardized Mortality Ratio measure will be submitted in a future cycle for endorsement by the CBE. Section 1886(b)(3)(B)(IX)(bb) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures that specifically measure sepsis mortality, therefore we believe the exception in Section 1886(b)(3)(B)(IX)(bb) of the Act applies.

## d. Request for Comment on Potential Future Use in the Hospital Inpatient Quality Reporting Program

We invite public input on the potential use of the Adult Community-Onset Sepsis Standardized Mortality Ratio measure, in addition to the following questions:

*Operational Considerations:*

- How feasible would it be for hospitals, especially those in rural areas, to implement and report on this measure using existing data and workflows? What data, workflow, or resource challenges do you anticipate? What is the single most important change you would recommend, if any?

- Do EHRs receive reconciled claims codes from payers or billing systems? Do EHR data reflect the claims-adjudicated codes or does it remain unchanged after claims are submitted? Are there any time lags or any other considerations for using the claims codes for sepsis surveillance and measure calculation as described above? If EHRs do receive reconciled claims from the billing systems, are they able to be represented in FHIR APIs?

- Do third-party vendors reconcile the claim codes? If so, how do these vendors receive data and submit data, what standards are used, and what is the frequency and cadence of data flow?

Please consider third-party vendors such as quality measurement vendors, health information exchanges, aggregators, EHR intermediaries, etc. who may normalize or reconcile claims (ICD-10, CPT, HCPCS) with clinical or FHIR-based data for reporting purposes.

- What are anticipated challenges in mapping EHR data to the specified Sepsis measure FHIR profiles and value sets? Please focus on data elements that may be unstructured (for example, are in narrative form), may be represented in local codes, or exist outside of commonly used documents that map to FHIR profiles (for example, flowsheets and provider orders). We refer readers to the NHSN digital quality measure information available at: <https://hl7.org/fhir/us/nhsn-dqm/> and <https://www.cdc.gov/nhsn/fhirportal/dqm/ig/>.

- Are there any additional anticipated challenges or burden related to: (1) making the required EHR data available in FHIR, (2) accessing and linking claims data needed for exclusions and risk adjustment, or (3) working with vendors or NHSN to implement the dQM specifications referenced above? Please provide details.

*Additional Policy Options:*

- To what extent do you believe this measure allows for fair comparison across hospitals? What adjustments or stratifications, if any, would improve fairness?

- To what extent do you agree this measure meaningfully reflects quality/value of care such that CMS should consider including this measure in a pay-for-performance program, such as the Hospital Value-Based Purchasing Program?

- Are there any potential unintended effects of using this measure for payment adjustment (for example, risk variable selection, reduced access to care, documentation burden)? If yes or not sure, please describe.

*C. Requirements for and Changes to the Hospital Inpatient Quality Reporting Program*

## 1. Background and History of the Hospital Inpatient Quality Reporting Program

The Hospital Inpatient Quality Reporting is a pay-for-reporting program intended to measure the quality of hospital inpatient services, improve the quality of care provided to Medicare beneficiaries, and facilitate public transparency. Section 1886(b)(3)(B)(viii) of the Social Security Act (the Act) states that subsection (d) hospitals participating in the Hospital Inpatient Quality Reporting Program that do not submit data required for measures

selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual payment update for the applicable fiscal year. We refer readers to our previous final rules for detailed discussions of the history of the Hospital Inpatient Quality Reporting Program, including statutory history, and for the measures we have previously adopted for the Hospital Inpatient Quality Reporting Program measure set.<sup>262</sup> We also refer readers to 42 Code of Federal Regulations (CFR) 412.140 for the Hospital Inpatient Quality Reporting Program regulations. We note that in the FY 2026 IPPS/LTCH PPS proposed rule, we discontinued the practice of retaining all subsections of the preamble every year where there are no proposed changes.

## 2. Considerations in Expanding and Updating Quality Measures

## (a) Background

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), in which we describe the Meaningful Measures Framework. In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, addressing a wide variety of settings, interested parties, and measure requirements.<sup>263</sup>

There are statutory requirements that the Secretary of HHS make public certain quality and efficiency measures that the Secretary is considering for adoption through rulemaking under Medicare.<sup>264</sup> To comply with those

<sup>262</sup> These rules are: the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861); the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 51653); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609); the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509); the FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959); the FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426); the FY 2023 IPPS/LTCH PPS final rule (87 FR 49190 through 49310); the FY 2024 IPPS/LTCH PPS final rule (88 FR 59144 through 59203); the FY 2025 IPPS/LTCH PPS final rule (89 FR 69515 through 69577); and the FY 2026 IPPS/LTCH PPS final rule (90 FR 36996 through 37027).

<sup>263</sup> Centers for Medicare & Medicaid Services. (2025). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: <https://www.cms.gov/medicare/quality/cms-national-quality-strategy/meaningful-measures-20-moving-measure-reduction-modernization>.

<sup>264</sup> See section 1890A(a)(2) of the Social Security Act (42 U.S.C. 1395aaa-1(a)(2)).



requirements, the consensus-based entity (CBE), currently Battelle, convenes the Partnership for Quality Measurement, which is comprised of clinicians, patients, measure experts, and health information technology specialists, to participate in the pre-rulemaking process and the measure endorsement process. We refer readers to the Partnership for Quality Measurement website<sup>265</sup> for a more detailed discussion on the updated Pre-rulemaking Measure Review process, as well as the endorsement and maintenance process.

### 3. Proposed New Measures for the Hospital Inpatient Quality Reporting Program Measure Set

We are proposing to adopt eight measures into the Hospital Inpatient Quality Reporting Program, three new measures, and five modified mortality measures as a step towards substantively modifying the mortality measures currently used in the Hospital Value-Based Purchasing Program: (1) Excess Days in Acute Care After Hospitalization for Diabetes measure beginning with the July 1, 2025 through June 30, 2027 performance period, associated with the FY 2029 payment determination; (2) Advance Care Planning electronic clinical quality measure (eCQM) beginning with the CY 2028 reporting period/FY 2030 payment determination; (3) Hospital Harm—Postoperative Venous Thromboembolism eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination; (4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization measure beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination; (5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization measure beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination; (6) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination; (7) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization measure beginning with the July 1, 2024 through June 30, 2026

performance period, associated with the FY 2028 payment determination; and (8) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft Surgery measure beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination. We provide more details on the proposed Excess Days in Acute Care After Hospitalization for Diabetes and the Hospital Harm—Postoperative Venous Thromboembolism eCQM in the subsequent sections of the preamble. Details on the proposed Advance Care Planning eCQM measure are in section IX.B.1., and details on the proposed five mortality measures are in section IX.B.2.

#### a. Proposed Adoption of the Excess Days in Acute Care After Hospitalization for Diabetes Measure

##### (1) Background

An estimated one in every three Americans 65 years or older has diabetes.<sup>266</sup> The American Diabetes Association estimated that in 2022, health care expenditures attributable to diabetes for individuals aged 65 years or older in the United States included \$67.7 billion for hospital inpatient stays and \$7.2 billion for emergency department (ED) visits.<sup>267</sup> Diabetes is one of the most expensive conditions billed to Medicare,<sup>268</sup> with wide variation in inpatient utilization among hospitals.<sup>269</sup> For Medicare beneficiaries, diabetes with complications is a leading Medicare principal discharge diagnosis and among the top five principal diagnoses for 30-day all-cause hospital readmissions.<sup>270</sup> Post-discharge ED

visits and observation stays are also common and costly for patients with diabetes,<sup>272</sup> often reflecting gaps in discharge coordination, patient education, medication management, and standardized post-discharge support.<sup>273</sup>

Hospitals can improve diabetes care quality with evidence-based, guideline-driven interventions. The American Diabetes Association recommends multiple key strategies as part of structured discharge planning, including diabetes self-management education, medication reconciliation, and scheduling follow-up appointments before the patient is discharged.<sup>274</sup> A review of interventions aimed at reducing readmissions for patients with type 2 diabetes concluded that diabetes management interventions that start at the index admission are highly effective.<sup>275</sup> Common strategies associated with effective interventions include multidisciplinary input, dedicated care transition teams, certified diabetes educator appointments post-discharge, and hospital-initiated discharge protocol development and implementation, among others.<sup>276</sup> Other recommended interventions include the use of dedicated inpatient diabetes teams and multi-component programs combining education, transition support, and outpatient follow-up.<sup>277</sup> Hospitals

Available at: <https://hcup-us.ahrq.gov/reports/statbriefs/SB307-508.pdf>.

<sup>272</sup> Rubin, D.J., & Shah, A.A. (2021). Predicting and Preventing Acute Care Re-Utilization by Patients with Diabetes. *Current Diabetes Reports*, 21(9), 34. Available at: <https://doi.org/10.1007/s11892-021-01402-7>.

<sup>273</sup> Cai, J. & Islam, M.S. (2023). Interventions incorporating a multi-disciplinary team approach and a dedicated care team can help reduce preventable hospital readmissions of people with type 2 diabetes mellitus: A scoping review of current literature. *Diabetic Medicine* 40(1), e14957. Available at: <https://doi.org/10.1111/dme.14957>.

<sup>274</sup> American Diabetes Association Professional Practice Committee. Recommendation 16.16 (structured discharge plan). Chapter 16. Diabetes Care in the Hospital: Standards of Care in Diabetes—2025. *Diabetes Care* 2025;48 (Suppl. 1):S321–S334. Available at: <https://doi.org/10.2337/dc25-S016>.

<sup>275</sup> Cai, J. & Islam, M.S. (2023). Interventions incorporating a multi-disciplinary team approach and a dedicated care team can help reduce preventable hospital readmissions of people with type 2 diabetes mellitus: A scoping review of current literature. *Diabetic Medicine* 40(1), e14957. Available at: <https://doi.org/10.1111/dme.14957>.

<sup>276</sup> Cai, J. & Islam, M.S. (2023). Interventions incorporating a multi-disciplinary team approach and a dedicated care team can help reduce preventable hospital readmissions of people with type 2 diabetes mellitus: A scoping review of current literature. *Diabetic Medicine* 40(1), e14957. Available at: <https://doi.org/10.1111/dme.14957>.

<sup>277</sup> Demidowich, A.P., Batty, K., Love, T., et al. (2021). Effects of a Dedicated Inpatient Diabetes Management Service on Glycemic Control in a Community Hospital Setting. *Journal of diabetes*

Continued

<sup>265</sup> Battelle, Partnership for Quality website. Available at: <https://p4qm.org>.

<sup>266</sup> Centers for Disease Control and Prevention (CDC). (May 15, 2024). National Diabetes Statistics Report. Available at: <https://www.cdc.gov/diabetes/php/data-research/index.html>.

<sup>267</sup> Parker, E.D., Lin, J., Mahoney, T., et al. (2024). Economic Costs of Diabetes in the U.S. in 2022. *Diabetes care*, 47(1), 26–43. Available at: <https://doi.org/10.2337/dci23-0085>.

<sup>268</sup> Liang, L. (AHRQ), Moore, B. (IBM Watson Health), Soni, A. (AHRQ). (July 2020). National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2017. HCUP Statistical Brief #261. Agency for Healthcare Research and Quality. Available at: [www.hcup-us.ahrq.gov/reports/statbriefs/sb261-Most-Expensive-Hospital-Conditions-2017.pdf](https://www.hcup-us.ahrq.gov/reports/statbriefs/sb261-Most-Expensive-Hospital-Conditions-2017.pdf).

<sup>269</sup> Rubin, D.J., & Shah, A.A. (2021). Predicting and Preventing Acute Care Re-Utilization by Patients with Diabetes. *Current Diabetes Reports*, 21(9), 34. Available at: <https://doi.org/10.1007/s11892-021-01402-7>.

<sup>270</sup> Agency for Healthcare Research and Quality (AHRQ). Healthcare Cost and Utilization Project (HCUPnet). Available at: <https://datatools.ahrq.gov/hcupnet/>.

<sup>271</sup> Jiang, H.J., & Barrett M.L. (April 2024). Clinical Conditions With Frequent, Costly Hospital Readmissions by Payer, 2020. Healthcare Cost and Utilization Project (HCUP) Statistical Brief #307. Agency for Healthcare Research and Quality.



that practice these interventions help to reduce post-discharge acute care utilization and other diabetes-related costs.<sup>279</sup>

There are currently no publicly reported measures of post-discharge care utilization for patients hospitalized for diabetes in the Hospital Inpatient Quality Reporting Program. Given the prevalence, care burden, and cost of diabetes, as well as the availability of effective interventions,<sup>280</sup> we propose to adopt the Excess Days in Acute Care After Hospitalization for Diabetes (Diabetes EDAC) measure into the Hospital Inpatient Quality Reporting Program beginning with the July 1, 2025 to June 30, 2027 performance period, associated with the FY 2029 payment determination. The proposed measure supports the CMS and HHS priority to address chronic illness while aiming to improve disease-specific outcomes, reduce avoidable acute-care utilization, and improve care transitions.<sup>281</sup>

## (2) Overview of Measure

The proposed Diabetes EDAC measure is a risk adjusted outcome measure that assesses the number of days a patient spends in acute care within 30 days of discharge from an inpatient hospitalization for a diagnosis of diabetes mellitus with complications. The measure is intended to improve the quality of care transitions provided to patients hospitalized for diabetes by collectively measuring different types of returns to the hospital (ED visits, observation stays, and unplanned readmissions), which are all adverse acute care outcomes that can occur at any time within 30 days of discharge.<sup>282</sup> We tested the proposed Diabetes EDAC measure using the most recent Medicare inpatient hospital discharge data from 4,193 hospitals with at least 25 eligible discharges from January 1, 2022, through December 31, 2023. Hospital-level performance rates are depicted in Table IX.C.1., and demonstrate there is meaningful variation in the distribution of the measure scores.<sup>283</sup> Similarly to the existing EDAC measures in the

Hospital Inpatient Quality Reporting Program for patients admitted for pneumonia, heart failure, or acute myocardial infarction, which calculate final risk adjusted measure scores as the difference (“excess”) between a hospital’s “predicted days” and “expected days,” per 100 discharges, lower scores (including negative numbers) indicate better performance. Thus, the lower performance percentiles are better performing hospitals than those in the higher percentiles (for example, the hospitals in the tenth percentile are the best performing hospitals). We note that in Table IX.C.1. negative numbers indicate fewer days than predicted in acute care. The interquartile range is 69.5 excess days in acute care per 100 discharges, and the difference between the 10th and 90th percentiles is 142.8 excess days in acute care per 100 discharges, occurring within 30 days of discharge from an inpatient hospitalization for diabetes.<sup>284</sup> For more details on the risk adjustment model, we refer readers to section IX.C.3.a.

**TABLE IX.C.1. HOSPITAL PERFORMANCE IN MEASURE TESTING FOR THE DIABETES EDAC MEASURE**

| Performance Percentile   | Risk-Adjusted Excess Days in Acute Care per 100 Discharges |
|--------------------------|------------------------------------------------------------|
| 10th Percentile          | -55.1                                                      |
| 25th Percentile          | -29.5                                                      |
| 50th Percentile (median) | 1.6                                                        |
| 75th Percentile          | 40.3                                                       |
| 90th Percentile          | 87.7                                                       |

Further, test results indicated measure reliability that meets accepted standards of reliability for a publicly reported measure.<sup>285</sup> In testing this measure, we observed a significant association with the expected strength and in the

expected direction with measures in the same causal pathway, which supports the validity of the Diabetes EDAC measure.<sup>286</sup> The Diabetes EDAC measure was designed with stakeholder feedback from a diverse Technical

Expert Panel (TEP).<sup>287</sup> During measure development, the TEP evaluated the measure’s face validity and expressed overall support, indicating that the Diabetes EDAC measure is a meaningful indicator of hospital quality.<sup>288</sup>

*science and technology*, 15(3), 546–552. Available at: <https://doi.org/10.1177/1932296821993198>.

<sup>278</sup> Bhalodkar, A., Sonmez, H., Lesser, M., et al. (2020). The Effects of a Comprehensive Multidisciplinary Outpatient Diabetes Program on Hospital Readmission Rates in Patients with Diabetes: A Randomized Controlled Prospective Study. *Endocr Pract.*, 26(11), 1331–1336. Available at: <https://doi.org/10.4158/EP-2020-0261>.

<sup>279</sup> American Diabetes Association Professional Practice Committee. (2025). Chapter 16. Diabetes care in the hospital: Standards of care in diabetes—2025. Diabetes Care, 48(Supplement 1). Available at: <https://doi.org/10.2337/dc25-S016>.

<sup>280</sup> American Diabetes Association Professional Practice Committee. (2025). Chapter 16. Diabetes care in the hospital: Standards of care in diabetes—2025. Diabetes Care, 48(Supplement 1). Available at: <https://doi.org/10.2337/dc25-S016>.

<sup>281</sup> U.S. Department of Health & Human Services. (2025). HHS Priorities. Available at: <https://www.hhs.gov/about/priorities/index.html>.

<sup>282</sup> QualityNet. Excess Days in Acute Care Measures Methodology. Available at: <https://qualitynet.cms.gov/inpatient/measures/edac/methodology>.

<sup>283</sup> Partnership for Quality Measurement. Diabetes EDAC Empiric Validity and Evidence of Performance Gap. Excess Days in Acute Care (EDAC) After Hospitalization for Diabetes. Available at: <https://www.p4qm.org/prmr-measures/muc2025-053>.

<sup>284</sup> Centers for Medicare & Medicaid Services. Diabetes EDAC Empiric Validity and Evidence of Performance Gap. Available at: <https://www.p4qm.org/sites/default/files/2025-12/MUC2025-053.zip>.

<sup>285</sup> Partnership for Quality Measurement. (Oct. 2025). National Consensus Development and Strategic Planning for Health Care Quality Measurement. Endorsement and Maintenance Guidebook. Available at: <https://www.p4qm.org/sites/default/files/2025-11/Del-3-6-Endorsement-and-Maintenance-Guidebook-OP2-508.pdf>.

<sup>286</sup> Partnership for Quality Measurement. Diabetes EDAC Empiric Validity and Evidence of Performance Gap. Excess Days in Acute Care (EDAC) After Hospitalization for Diabetes. Available at: <https://www.p4qm.org/prmr-measures/muc2025-053>.

<sup>287</sup> Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. (Oct. 2024). Summary of Technical Expert Panel (TEP) Diabetes Excess Days in Acute Care (EDAC). Available at: <https://mmshub.cms.gov/sites/default/files/Diabetes-EDAC-TEP-Meetings-Summary-Report.pdf>.

<sup>288</sup> Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. (Oct. 2024). Summary of Technical Expert Panel (TEP) Diabetes Excess Days in Acute Care (EDAC). Available at: <https://mmshub.cms.gov/sites/default/files/Diabetes-EDAC-TEP-Meetings-Summary-Report.pdf>.

## (3) Measure Calculation

The final risk adjusted Diabetes EDAC measure score is calculated as the difference, or “excess” days, between a hospital’s “predicted” days (that is, the average number of days a patient spent in acute care after adjusting for the risk factors) and “expected” days (that is, the average number of risk adjusted days in acute care a patient would have been expected to spend if discharged from an average-performing hospital with the same case mix), per 100 discharges. The measure result is multiplied by 100, such that the final Diabetes EDAC measure score would represent excess days in acute care per 100 discharges and is reported as a rate.

## (a) Numerator

The numerator for the proposed Diabetes EDAC measure is defined as the number of days a patient spends in acute care for any cause, within 30 days of discharge from the index hospitalization for diabetes. Days in acute care are defined as time spent in: ED visits without an associated admission, observation stays, and unplanned readmissions.<sup>289</sup> Utilization is measured in days; each ED visit counts as one full day, regardless of duration or whether it spans more than one calendar date. Observation stays are measured in hours and rounded up to the nearest whole day; for example, a 28-hour observation stay counts as two full days. Unplanned readmissions are counted in days based on length of the hospital stay. All eligible encounters occurring within the 30-day period are counted, even if repeated. For example, an unplanned readmission with a length of stay of 7 days and an ED visit without an associated admission, both within 30 days of discharge, would contribute 8 days toward the EDAC numerator. Planned readmissions, such as scheduled follow-up visits, elective surgeries, or chemotherapy, are excluded. Consistent with existing EDAC measures, a planned readmission algorithm identifies admissions typically scheduled within 30 days of discharge.

## (b) Denominator

This measure denominator includes index admissions for patients who meet all of the following criteria:

- Principal discharge diagnosis of diabetes;
- Enrolled in Medicare Fee-For-Service or Medicare Advantage for the

12 months prior to the date of admission and during the index admission;

- Aged 65 or over;
- Discharged alive from a non-federal short-term acute care hospital; and
- Not transferred to another acute care facility.

The measure excludes the following index admissions from the measure cohort: (1) hospitalizations without at least 30 days of post-discharge enrollment in Medicare Fee-For-Service or Medicare Advantage; (2) discharged against medical advice; or (3) diabetes admissions within 30 days of discharge from a prior diabetes index admission. These exclusion criteria are similar to those of the existing EDAC measures in the Hospital Inpatient Quality Reporting Program.

## (c) Risk-Adjustment

To account for differences in case mix among hospitals, the measure risk adjusts for age, comorbidities, severity of illness, and frailty based on clinical status at the index admission. The measure’s risk adjustment includes comorbidities present at admission or within the prior 12 months, excludes complications arising during hospitalization, and accounts for survival times shorter than 30 days post discharge to accurately reflect hospital performance.

For more information regarding the proposed Diabetes EDAC measure specifications, we refer readers to the Hospital Inpatient Proposed Measures web page at <https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures>.

## (4) Pre-Rulemaking Process and Measure Endorsement

## (a) Recommendation From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement for details on the Pre-rulemaking Measure Review process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.<sup>290 291</sup> The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-

Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available “2025 Measures Under Consideration List,” including the Diabetes EDAC measure (MUC2025–053).<sup>292</sup>

The voting results of the Recommendation Group for the proposed inclusion of the Diabetes EDAC measure in the Hospital Inpatient Quality Reporting Program were: 15 members (68 percent) recommended adopting the measure into the Hospital Inpatient Quality Reporting Program; 7 members (32 percent) voted not to recommend the measure for adoption.<sup>293</sup> With 68 percent of the votes for recommend, consensus was not reached, but the majority of the Recommendation Group expressed some support for use of the measure in the Hospital Inpatient Quality Reporting Program.

Recommendation Group members who voted to recommend the measure for inclusion in the Hospital Inpatient Quality Reporting Program emphasized its importance for patients hospitalized for diabetes. Some Recommendation Group members provided considerations along with their vote to recommend this measure. Considerations included improved discharge planning and shortening the accountability window to a 7-day post-discharge period. Another member recommended adding sociodemographic risk factors to the risk adjustment model. Members also recommended expanding the measure to a hospital-wide approach, rather than a condition-specific approach.

Recommendation Group members who voted not to recommend the measure for inclusion in the Hospital Inpatient Quality Reporting Program provided the following rationales: (1) hospitals have limited control over outpatient access or follow-up care; (2) the 30-day post-discharge period may not be appropriate; (3) the risk adjustment should be evaluated to ensure it is sufficient; (4) the measure

<sup>290</sup> Partnership for Quality Management. Pre-Rulemaking Measure Review web page. Available at: <https://p4qm.org/prmr/about>.

<sup>291</sup> In 2025, the CBE updated the Pre-Rulemaking Measure Review voting process such that Recommendation Group members will vote to either “recommend” or “do not recommend” that a measure be added to the intended CMS program(s), thus, removing the “recommend with conditions” voting option. The threshold to reach consensus on a given measure continues to be a minimum of 75 percent agreement among members. Recommendation Group members can provide considerations for CMS to review prior to implementation.

<sup>292</sup> Centers for Medicare & Medicaid Services. (2025). 2025 Measures Under Consideration List. Available at <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

<sup>293</sup> Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendations Group Final Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

<sup>289</sup> Partnership for Quality Measurement. Excess Days in Acute Care (EDAC) After Hospitalization for Diabetes. Available at: <https://www.p4qm.org/prmr-measures/muc2025-053>.

should undergo additional testing and have clearer specifications; and (5) the measure should be submitted for endorsement.

Regarding concerns related to hospitals' limited control over outpatient access or follow-up care, we wish to emphasize that an effective strategy for improving avoidable post-discharge acute-care utilization is to connect patients to resources as part of discharge planning. For example, one of the key strategies recommended by the American Diabetes Association is scheduling follow-up appointments before the patient is discharged.<sup>294</sup> We consider these types of activities to be an important part of providing high quality care for patients with diabetes, and note that a goal of this measure is to incentivize hospitals to ensure these types of activities are standard practices. Through detailed, confidential, hospital-specific reports, hospitals would be provided with data to show where there are opportunities for improvement.

Regarding concerns and considerations related to the post-discharge period for accountability, the measure's 30-day timeframe is consistent with the existing 30-day readmission and EDAC measures in the Hospital Inpatient Quality Reporting Program, which have been endorsed by a CBE and publicly reported. The 30-day timeframe allows for a more complete reflection of the hospital's full discharge plan, including follow-up, care coordination, and self-management education.

Regarding concerns about the sufficiency of the measure's risk adjustment model, measure testing supported the current risk adjustment model. The Diabetes EDAC measure is risk adjusted for clinically relevant factors including patient functional status (frailty indicator), patient-level demographics (age), and patient-level health status and clinical conditions (case-mix adjustment, comorbidities, and severity of illness).<sup>295</sup> The risk adjustment model testing results indicate adequate controls for differences in patient characteristics (case mix), with a c-statistic<sup>296</sup> of 0.68,

and 0.70 in the validation sample. The predictive ability<sup>297</sup> ranged from 1.66 percent to 13.23 percent, and 1.22 percent to 14.43 percent in the validation sample.<sup>298</sup> These testing results demonstrate the risk adjustment model effectively differentiates excess days in acute care after hospitalization for diabetes, thus adequately adjusting for differences in patient characteristics.<sup>299</sup> Regarding the recommendation to include sociodemographic risk factors, we tested model performance using dual-eligible status. Overall, the results indicate that the impact of dual-eligible status on measures scores is minimal and did not meaningfully change hospital scores. This informed our decision not to adjust for dual-eligible status in the risk adjustment model.<sup>300</sup>

Regarding concerns about additional testing, a recommendation for clearer specifications, and concerns about lack of endorsement, we note that the measure underwent the same extensive analysis and measure specifications development needed for the endorsement process, and that the measure will be submitted to the CBE for endorsement review for the Spring 2026 review cycle.

Regarding the consideration to expand this measure to a hospital-wide approach, rather than a condition-specific approach, we thank the Recommendation Group for this

those patients who have and have not had a qualifying event within 30 days. Potential values range from 0.5, meaning no better than chance, to 1.0, an indication of perfect prediction. The CBE has determined that for readmission-type measures, a c-statistic of 0.68 is considered an effective model of discriminant ability. We refer readers to the "Diabetes EDAC Risk Adjustment and Model Performance Testing" available at: <https://p4qm.org/prmr-measures/muc2025-053> for more details.

<sup>297</sup> Predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects. A model with good predictive ability would see a wide range in observed outcomes between lowest and highest deciles of predicted outcomes. We have calculated the range of mean observed hospital ratios between the lowest and highest deciles of hospital visit probabilities. We refer readers to the "Diabetes EDAC Risk Adjustment and Model Performance Testing" available at: <https://p4qm.org/prmr-measures/muc2025-053> for more details.

<sup>298</sup> Centers for Medicare & Medicaid Services. (2025). Diabetes EDAC Risk Adjustment and Model Performance Testing. Available at: <https://www.p4qm.org/sites/default/files/2025-12/MUC2025-053.zip>.

<sup>299</sup> Centers for Medicare & Medicaid Services. (2025). Diabetes EDAC Risk Adjustment and Model Performance Testing. Available at: <https://www.p4qm.org/sites/default/files/2025-12/MUC2025-053.zip>.

<sup>300</sup> Centers for Medicare & Medicaid Services. (2025). Diabetes EDAC Risk Adjustment and Model Performance Testing. Available at: <https://www.p4qm.org/sites/default/files/2025-12/MUC2025-053.zip>.

consideration and will consider it for future measures.

After taking these recommendations and concerns into consideration, we propose to adopt the Diabetes EDAC measure into the Hospital Inpatient Quality Reporting Program beginning with the July 1, 2025 to June 30, 2027 performance period, associated with the FY 2029 payment determination.

#### (b) Measure Endorsement

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The Diabetes EDAC measure will be submitted to the CBE for endorsement review for the Spring 2026 cycle. Section 1886(b)(3)(B)(viii)(IX)(aa) of the Social Security Act (Act) generally requires that measures specified by the Secretary for use in the Hospital Inpatient Quality Reporting Program be endorsed by the entity with a contract under section 1890(a) of the Act. However, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any CBE-endorsed hospital inpatient measures addressing post-discharge care utilization for patients hospitalized for diabetes. Therefore, the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

#### (5) Data Sources, Submission, and Public Reporting

The proposed Diabetes EDAC measure uses claims data from Medicare Fee-For-Service and Medicare Advantage encounter data which are routinely generated by hospitals and Medicare Advantage plans and submitted to CMS. Therefore, hospitals would not be required to report any additional data for this measure. Enrollment status would be obtained from the Medicare Enrollment Database which contains beneficiary demographic, benefit/coverage, and vital status information.

While the existing EDAC measures in the Hospital Inpatient Quality Reporting

<sup>294</sup> American Diabetes Association Professional Practice Committee. Recommendation 16.16 (structured discharge plan). Chapter 16. Diabetes Care in the Hospital: Standards of Care in Diabetes—2025. Diabetes Care 2025;48 (Suppl. 1):S321–S334. Available at: <https://doi.org/10.2337/dc25-S016>.

<sup>295</sup> Centers for Medicare & Medicaid Services. (2025). Diabetes EDAC Risk Adjustment and Model Performance Testing. Available at: <https://www.p4qm.org/sites/default/files/2025-12/MUC2025-053.zip>.

<sup>296</sup> The c-statistic is an indicator of the model's discriminant ability or ability to correctly classify

Program currently use a 3-year performance period, in section IX.C.5.a. of this FY 2027 IPPS/LTCH PPS proposed rule, we are proposing to add Medicare Advantage beneficiaries to the measure cohorts and shorten the performance periods to 2 years. To align with these proposed updates, we propose that the Diabetes EDAC measure would also use a 2-year performance period. For example, for the FY 2029 payment determination, the performance period would comprise of data for index admissions that occurred between July 1, 2025 to June 30, 2027. The measure would be publicly reported through the Compare tool, currently available at: <https://www.medicare.gov/care-compare/>, or successor CMS website, for the first time in July 2028, or as soon as feasible. The measure would be calculated and publicly reported on an annual basis using a rolling 24-months performance period data.

We invite public comment on our proposal to adopt the Diabetes EDAC measure into the Hospital Inpatient Quality Reporting Program beginning with the July 1, 2025 to June 30, 2027 performance period, associated with the FY 2029 payment determination.

#### b. Proposed Adoption of the Hospital Harm—Postoperative Venous Thromboembolism Electronic Clinical Quality Measure

##### (1) Background

Postoperative venous thromboembolism (VTE) includes both deep vein thrombosis (DVT), a thrombus (that is, blood clot) in the deep veins, most often in the legs, and pulmonary embolism (PE), when a thrombus travels through the venous circulation and the right side of the heart, and lodges in the lungs. VTE is considered to be a leading cause of preventable death following surgery, with as many as 70 percent of cases considered to be preventable.<sup>301</sup> Non-fatal postoperative VTE can lead to adverse health consequences, including chronic thromboembolic pulmonary hypertension, a potentially fatal condition. Long term complications, such as pain and swelling in the affected limb, occur among one third to one half of people who have had a DVT and one third of VTE patients will experience a recurrence of the DVT within 10 years.<sup>302</sup> The AHRQ

Healthcare Cost and Utilization Project (HCUP) State Inpatient Database from 2020, 2021, and 2022 showed that 50,017 perioperative PE's or DVT's occurred in 15,387,213 discharges, which is a rate of 3.25 per 1,000 discharges.<sup>303</sup> Each postoperative VTE event generates an estimated \$17,367 in additional costs,<sup>304</sup> suggesting a 3-year cost of \$868,645,239 for the postoperative VTE events identified in the HCUP data. An analysis of 1,112,014 hospitalizations between 2013 and 2021 found a more than three times higher risk of readmission and a 63 percent higher risk of death for patients acquiring a hospital-associated VTE.<sup>305</sup>

There are established therapies that can reduce the risk of a VTE, but failure or delay in prescribing appropriate VTE prophylaxis can result in a higher risk of postoperative VTE. For example, one study found that delays or interruptions in thromboprophylaxis were associated with two to three times higher risk of VTE.<sup>306</sup> Hospital care processes can reduce the risk of hospital-acquired VTE through integration of evidence-based guidelines into hospital protocols and use of VTE-risk assessment and physician alerts to improve use of VTE prophylaxis.<sup>307</sup> Another report found evidence that combining hospital interventions, such as mechanical and pharmacological prophylaxis, can reduce the incidence of DVT among patients undergoing surgery or admitted with trauma.<sup>308</sup> This volume of

(Blood Clots). Available at: <https://www.cdc.gov/blood-clots/data-research/facts-stats/index.html>.

<sup>303</sup> Agency for Healthcare Research and Quality. Patient Safety Indicators (PSI) Benchmark Data Tables, v. 2025. AHRQ PSI Technical Documentation, Version v2025. Available at: [https://qualityindicators.ahrq.gov/measures/psi\\_resources](https://qualityindicators.ahrq.gov/measures/psi_resources).

<sup>304</sup> Agency for Healthcare Research and Quality. (2020). AHRQ National Scorecard on Hospital-Acquired Conditions. Available at: <https://www.ahrq.gov/hai/pfp/index.html>.

<sup>305</sup> Neeman E, Liu V, Mishra P, et al. Trends and Risk Factors for Venous Thromboembolism Among Hospitalized Medical Patients. *JAMA Net Open*. 2022;5(11):e2240373. Available at: doi:10.1001/jamanetworkopen.2022.40373.

<sup>306</sup> Henke, P.K., Kahn, S.R., Pannucci, C.J., Secemsky, E.A., Evans, N.S., Khorana, A.A., Creager, M.A., & Pradhan, A.D. (2020). Call to action to prevent venous thromboembolism in hospitalized patients: A policy statement from the American Heart Association. *Circulation*, 141(24). Available at: <https://doi.org/10.1161/cir.0000000000000769>.

<sup>307</sup> Geerts, W. (2009). Prevention of venous thromboembolism: a key patient safety priority. *Journal of Thrombosis and Haemostasis*, 7, 1–8. Available at: <https://www.sciencedirect.com/science/article/pii/S1538783622174040>.

<sup>308</sup> Kakkos, S., Kirkilesis, G., Caprini, J. A., Geroulakos, G., Nicolaidis, A., Stansby, G., & Reddy, D. J. (2022). Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism. *The Cochrane database of*

preventable safety events shows that there are opportunities to reduce the rate of postoperative VTEs.

Preventing VTE and associated complications after hospitalization and incentivizing appropriate administration of VTE prophylaxis have been, and continue to be, important goals of the Hospital Inpatient Quality Reporting Program since the early days of the program. The current measure set contains two VTE eQMs, Venous Thromboembolism Prophylaxis (VTE–1) eQM and Intensive Care Unit Venous Thromboembolism Prophylaxis (VTE–2) eQM, which were adopted as measures that hospitals could self-select beginning with the CY 2014 reporting period (78 FR 50807 through 50810). Replacing these two process measures with a single comprehensive outcome measure can reduce burden while continuing to address this consequential health care issue affecting postoperative patient outcomes.

We propose to adopt the Hospital Harm—Postoperative Venous Thromboembolism (hereafter referred to as Hospital Harm—Postoperative VTE) eQM beginning with the CY 2028 reporting period/FY 2030 payment determination. We refer readers to section IX.C.4.a. for our proposal to remove the VTE–1 and VTE–2 eQMs contingent upon the adoption of the Hospital Harm—Postoperative VTE eQM.

##### (2) Overview of Measure

The Hospital Harm—Postoperative VTE eQM is a risk adjusted outcome measure that assesses the proportion of inpatient hospitalizations for patients age 18 and older who have at least one surgical procedure performed inside the operating room during the admission, and who suffer the harm of a postoperative VTE during hospitalization or within 30 days after the first surgical procedure. The intent of the measure is to improve patient safety by incentivizing hospitals to implement processes to reduce the occurrence of postoperative VTE. Accurately monitoring the rate at which postoperative VTE occurs will allow hospitals to improve quality and reduce VTE harm rates.

##### (3) Measure Calculation

This outcome measure reports the proportion of inpatient hospitalizations for patients aged 18 years and older with a postoperative VTE within 30

systematic reviews, 1(1), CD005258. Available at: <https://doi.org/10.1002/14651858.CD005258.pub4>.

<sup>301</sup> Centers for Disease Control and Prevention. (2025). Data and Statistics on Venous Thromboembolism. In *Venous Thromboembolism (Blood Clots)*. Available at: <https://www.cdc.gov/blood-clots/data-research/facts-stats/index.html>.

<sup>302</sup> Centers for Disease Control and Prevention. (2025). Data and Statistics on Venous Thromboembolism. In *Venous Thromboembolism*

days of the first surgical procedure.<sup>309</sup> This measure is calculated using a risk adjusted measure score, which reflects the performance of a hospital treating its patients relative to the average hospital treating patients with the same characteristics. This is calculated by:

- Dividing the number of inpatient hospitalizations in the numerator by the number of inpatient admissions in the denominator to determine the observed rate;
- Using the risk adjustment model to determine the hospital's expected VTE event rate based on the hospital's case mix; and
- Dividing the observed rate by the expected rate.

#### (a) Numerator

The numerator is the number of inpatient hospitalizations for adult patients who had a surgical procedure performed in the operating room during the hospitalization and experienced a VTE within 30 days of the surgical procedure. Postoperative VTE cases can be identified for inclusion in the numerator in multiple ways. For example, documentation in the medical record of a diagnosis of VTE that was not present when the patient was admitted to the hospital for an inpatient stay that included surgery would qualify the admission for the numerator. Alternatively, an inpatient admission in which a patient had surgery and subsequently had a diagnostic imaging procedure performed followed by an order for anticoagulation therapy would also qualify for the numerator. A postoperative VTE that occurs during a subsequent hospital stay within 30 days of the surgical procedure would count toward the numerator if there is documentation of a diagnosis of VTE and anticoagulation therapy ordered or prescribed during that hospital stay. We refer readers to the Partnership for Quality Measurement website (<https://p4qm.org/prmr-measures/muc2025-067>) for more details on the measure specifications, including more details on how a postoperative VTE is determined.

#### (b) Denominator

The denominator is the number of adult patients who had a surgical procedure performed in the operating

room during an inpatient hospitalization. The cohort includes inpatient hospitalizations for patients aged 18 and older where a surgical procedure was performed inside the operating room during the encounter. The cohort excludes inpatient encounters for:

- Patients with an obstetric-related diagnosis;
- A VTE diagnosis present on admission;
- Acute brain or spinal injury or hemorrhage present on admission;
- Extracorporeal membrane oxygenation during the inpatient encounter;
- A thrombectomy procedure before or on the same day as the first surgical procedure;
- Intracranial or spinal surgery where the patient was discharged less than five days after the end of the surgery; and
- Inpatient encounters with a duration of stay less than 2 days.

#### (c) Risk Adjustment

The risk adjustment model accounts for factors that affect risk of VTE, specifically age, sex, and eight clinical factors (bleeding disorders, cancer, catheter insertion, history of VTE, obesity, respiratory operations, stroke, and vascular surgeries). The risk adjustment model was developed using two consecutive years (CY 2022 through 2023) of electronic health record (EHR) data from a commercially available EHR database.<sup>310</sup> Testing of the risk adjustment model demonstrated the ability to discriminate between high-risk and low-risk postoperative VTE events. The risk adjustment model has been developed to ensure that hospitals that care for patients at higher risk of postoperative VTE are evaluated fairly.<sup>311</sup>

The sample to evaluate the risk adjustment model included 100,911 hospitalizations from 34 hospitals in six states during 2022 and 2023. Hospital-level characteristics were not available because the data uses anonymized hospital identifications. Hospitals included in the sample had hospitalizations ranging in number from 56 to 6,746 annually.<sup>312</sup> The risk adjusted performance scores ranged

from 0.21 percent in Decile 1 to 4.21 percent in Decile 10, with a median score of 0.78 percent.<sup>313</sup> The difference between the best and worst performing facilities suggests there is room for improvement among facilities. In addition, the median performance score of 0.78 percent exceeds the rate of 0.35 percent found in the AHRQ HCUP State Inpatient Database.<sup>314</sup> The testing results using 2 years of data (CY 2022 through 2023) indicated strong measure reliability, with signal-to-noise reliability scores ranging from 0.9998 to 0.9999, and therefore this measure demonstrates high reliability using 2 years of data.<sup>315</sup> Data element validity testing was conducted with two hospitals and results from this testing showing strong agreement between EHR data and patient chart-abstracted data for nearly all data elements and moderate to excellent sensitivity and specificity results for classifying patients into the denominator and numerator. There was moderate to low sensitivity for classifying patients as denominator exclusions, but these findings were likely driven by specific limitations of the hospitals involved in testing rather than indicative of broader validity limitations.

#### (4) Pre-Rulemaking Process and Measure Endorsements

##### (a) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement website for details on the Pre-rulemaking Measure Review process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.<sup>316 317</sup> The Pre-rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter

<sup>313</sup> Partnership for Quality Measurement. Under the Performance Gap, under Importance Tab. Available at: <https://p4qm.org/measures/5325e>.

<sup>314</sup> Agency for Healthcare Research and Quality. Patient Safety Indicators (PSI) Benchmark Data Tables, v. 2025. AHRQ PSI Technical Documentation, Version v2025. Available at: [https://qualityindicators.ahrq.gov/measures/psi\\_resources](https://qualityindicators.ahrq.gov/measures/psi_resources).

<sup>315</sup> Partnership for Quality Measurement. Reliability web page, under the Scientific Acceptability Tab, Hospital Harm—Postoperative Venous Thromboembolism. Available at: <https://p4qm.org/measures/5325e>.

<sup>316</sup> Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. Available at: <https://p4qm.org/prmr/about>.

<sup>317</sup> We note the Pre-Rulemaking Measure Review voting process was updated in 2025. We refer readers to the corresponding footnote in section IX.C.3.a.(4).(a). of this proposed rule for details on the updated Pre-Rulemaking Measure Review voting process.

<sup>309</sup> This criterion was supported by the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP). Information about this program is available at: [https://www.surgeons.org/-/media/Project/RACS/surgeons.org/files/interest-groups-sections/surgical-directors/199778\\_2016-08-20\\_pre\\_bruce\\_hodge\\_nsqip.pdf?rev=ef1c0da899bf442aa5cdf711ba24155b&hash=65855EF1169A93A4C83471DA384DAF57](https://www.surgeons.org/-/media/Project/RACS/surgeons.org/files/interest-groups-sections/surgical-directors/199778_2016-08-20_pre_bruce_hodge_nsqip.pdf?rev=ef1c0da899bf442aa5cdf711ba24155b&hash=65855EF1169A93A4C83471DA384DAF57).

<sup>310</sup> Partnership for Quality Measurement. Measurement Data Report, Downloads, Hospital Harm—Postoperative Venous Thromboembolism. Available at: <https://p4qm.org/measures/5325e>.

<sup>311</sup> Partnership for Quality Measurement. Risk Adjustment, under the Scientific Acceptability Tab, Hospital Harm—Postoperative VTE. Available at: <https://p4qm.org/measures/5325e>.

<sup>312</sup> Partnership for Quality Measurement. Scientific Acceptability Tab, Hospital Harm—Postoperative VTE. Available at: <https://p4qm.org/measures/5325e>.

referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available “2025 Measures Under Consideration List,” including the Hospital Harm—Postoperative VTE measure.<sup>318</sup>

The voting results of the Recommendation Group for the proposed adoption of the Hospital Harm—Postoperative VTE measure in the Hospital Inpatient Quality Reporting Program were: 7 members (35 percent) recommended adopting the measure into the Hospital Inpatient Quality Reporting Program, and 13 members (65 percent) voted not to recommend the measure for adoption.<sup>319</sup> With 65 percent of the votes not to recommend, consensus was not reached, with the majority of the Recommendation Group expressing some concern about use of the measure in the Hospital Inpatient Reporting Program.

Some Recommendation Group members who voted to support adoption of the Hospital Harm—Postoperative VTE measure in the Hospital Inpatient Quality Reporting Program provided several considerations with their vote. These considerations were concerns regarding the proposed 30-day window, concern that the timeline for adoption is unclear, and a recommendation to test the measure in additional EHR systems.

Recommendation Group members who voted not to recommend provided the following rationales: (1) concerns regarding the proposed 30-day timeframe; (2) concerns regarding potential overlap with the PSI 12 measure; (3) concerns regarding potential unintended consequences; (4) recommendations for methodological refinements; (5) concerns regarding technical implementation within EHR systems; (6) lack of clarity regarding the measure’s ability to meaningfully advance quality; and (7) concerns that the measure has not been endorsed by the Consensus Based Entity (CBE). We address each of these concerns in detail in the following paragraphs.

Regarding concerns that the timeline for adoption is unclear, we note that we are proposing to adopt the Hospital

Harm—Postoperative VTE measure beginning with the CY 2028 reporting period/FY 2030 payment determination as an option for self-selection. That is, participating hospitals may select the Hospital Harm—Postoperative VTE measure as one of the three self-selected eQMs to be reported in addition to three mandatory eQMs. We refer readers to Table IX.C.5 for the full list of eQMs available for self-selection. In addition, in section IX.C.8.c.(3). of the preamble of this proposed rule, we are proposing that Hospital Harm eQMs would become mandatory after two years of being an option for self-selection. If that policy is finalized, the Hospital Harm—Postoperative VTE measure would become mandatory beginning with the CY 2030 reporting period/FY 2032 payment determination.

Regarding the recommendation to test the measure in additional EHR systems, we used test sites collectively using four EHR systems (specifically, Epic, Allscripts, Cerner, and Meditech) which represent the majority of EHR systems in the United States.<sup>320</sup> We refer readers to section IX.C.3.b.(3).(c). for details on measure testing, including measure reliability and validity. If this eQM is finalized for adoption into the Hospital Inpatient Quality Reporting Program, we note that as a part of routine measure maintenance we conduct ongoing monitoring and evaluation of our measures to identify potential unintended consequences.

With respect to the 30-day timeframe, we note that 30 days post-discharge is a common window for assessing adverse events stemming from a hospital admission. The Hospital Inpatient Quality Reporting Program includes several measures that cover the 30-day period post discharge, such as the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications Measure and the Hybrid Hospital-Wide All-Cause Readmission Measure. With respect to using a 30-day timeframe for capturing postoperative VTE events, evidence shows that roughly one third of VTEs occur between postoperative day 14 and the end of the fourth week after surgery.<sup>321</sup>

We understand the concern regarding potential overlap with PSI 12, which is a claims-based measure of perioperative PE and DVT rate included in the PSI–90 composite, and only captures care provided for Medicare beneficiaries. The Hospital Harm—Postoperative VTE measure is an all-payer eQM, and therefore captures care provided for all patients rather than Medicare patients only. For this reason, we believe this measure has the potential to serve as a replacement for the claims-based PSI 12 measure in the future.

With respect to concerns about unintended consequences, including overtreatment and unnecessary use of anticoagulation therapies, we note that as a part of routine measure maintenance we conduct ongoing monitoring and evaluation of our measures to identify potential unintended consequences. Furthermore, we may consider adopting a measure focused on overuse of anticoagulation medication in future measure development and rulemaking.

Members of the Recommendation Group who suggested methodological refinements specifically recommended including clearer diagnostic criteria for VTE. The measure specifies that a stay must have documentation of both an imaging procedure to diagnose the VTE and initiation of anticoagulant therapy within 24 hours of the imaging procedure. The measure further requires that the anticoagulant therapy be delivered at a dose appropriate for therapeutic treatment of VTE, as opposed to a lower dose appropriate for VTE prophylaxis or maintenance therapy for atrial fibrillation. In concert, the three numerator requirements—(a) documentation of a diagnostic imaging procedure, (b) administration of anticoagulant therapy within 24 hours of the imaging procedure, and (c) for the anticoagulant to be provided at a dose consistent with VTE treatment—would minimize the chance for misclassification. We refer readers to the eCQI Resource Center ([https://ecqi.healthit.gov/eh-cah?qt-tabs\\_eh=1](https://ecqi.healthit.gov/eh-cah?qt-tabs_eh=1)) for more details on the measure specifications, including more details on how a postoperative VTE is determined.

Members of the Recommendation Group who had concerns regarding technical implementation in EHRs were concerned that hospitals in systems with a single enterprise-wide EHR may appear to perform worse on the measure because post-discharge VTE events are more likely to be captured. We note that

<sup>318</sup> Centers for Medicare & Medicaid Services. (2025). 2025 Measures Under Consideration List. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview>.

<sup>319</sup> Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary: Hospital Committees. Available at: <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

<sup>320</sup> Holmgren AJ, Apathy NC. (2023). Trends in US Hospital Electronic Health Record Vendor Market Concentration, 2012–2021. *J Gen Intern Med. Journal of general internal medicine*, 38(7), 1765–1767. Available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC10212829/>.

<sup>321</sup> Singh, T., Lavikainen, L.I., Halme, A.L.E., Aaltonen, R., Agarwal, A., Blanker, M. H., Bolsunovskiy, K., Cartwright, R., García-Perdomo, H., Gutschon, R., Lee, Y., Pourjamaal, N., Vernooij, R.W.M., Violette, P.D., Haukka, J., Guyatt, G.H., & Tikkinen, K. A. O. (2023). Timing of symptomatic venous thromboembolism after surgery: meta-analysis. *British Journal of Surgery*, 110(5), 553–

561. Available at: <https://doi.org/10.1093/bjs/znad035>.

this measure relies on capturing data regarding an imaging procedure to diagnose the VTE and initiation of anticoagulant therapy within 24 hours of the imaging procedure within the same EHR system in which the qualifying surgery was documented, which may cause systems with multiple EHRs to appear to perform better on this measure because they capture fewer post-discharge VTE events. However, given that many numerator-qualifying VTE events occur during the initial hospitalization, and approximately 75 percent of patients with post-surgical complications return to their discharging hospital,<sup>322 323</sup> we expect that the vast majority of data on postoperative VTEs would be available within the reporting hospital's EHR.

With respect to questions about how the Hospital Harm—Postoperative VTE measure advances quality, adopting a measure that evaluates the frequency of postoperative VTEs incentivizes hospitals to evaluate their current procedures and implement quality improvement initiatives to reduce the occurrences of this preventable condition.

With respect to concerns raised by Recommendation Group members that the measure had not been endorsed by the CBE, the Hospital Harm—Postoperative VTE measure was submitted to the CBE for the Fall 2025 endorsement cycle. We note that the CBE had not yet met to review the Hospital Harm—Postoperative VTE measure for endorsement at the time of the Recommendation Group review, but it subsequently did so and endorsed the measure. We refer readers to section IX.C.3.b.(4).(b). of this proposed rule for a further discussion of the results of the CBE's endorsement decision.

After taking these recommendations and concerns into consideration, we propose to adopt the Hospital Harm—Postoperative VTE measure in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination.

#### (b) Measure Endorsement

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The Hospital Harm—Postoperative VTE eCQM was submitted for review in the Fall 2025 cycle. The Management of Acute and Chronic Conditions Recommendation Group reviewed the Hospital Harm—Postoperative VTE eCQM (CBE# 5325e) on February 4, 2026. The voting results of the Recommendation Group were: 2 members (11 percent) voted to endorse the measure; 15 members (79 percent) voted to endorse the measure with conditions; and 2 members (11 percent) voted not to endorse the measure. With more than 75 percent of members voting to endorse the measure or endorse the measure with conditions, the Recommendation Group reached consensus to endorse the measure with conditions.<sup>324</sup> The condition is that by the next measure maintenance review (5 years) the developer will have explored other risk factors that may impact post-discharge VTE (for example, social determinants of health). In connection with this condition, we will continue to monitor and evaluate the risk adjustment methodology to determine if changes are needed.

#### (5) Data Source, Submission, and Public Reporting

The Hospital Harm—Postoperative VTE eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' certified health IT using the patient-level data and then submitted by hospitals to CMS. All data elements necessary to calculate the measure, including the numerator and denominator as well as to apply the risk adjustment model, are defined within value sets available in the Value Set Authority Center.<sup>325</sup> Testing was performed to confirm the feasibility of the measure, data elements, and validity of the numerator, using clinical adjudicators who validated the EHR

data compared with medical chart-abstracted data. Testing in six hospitals using three EHR systems demonstrated that all critical data elements can be reliably and consistently captured, and measure implementation is feasible.

We refer readers to section IX.C.8.c. of this proposed rule for discussion of previously finalized eCQM reporting and submission policies, and our proposed modifications to establish mandatory reporting of all Hospital Harm eCQMs after an initial period of voluntary reporting in the program. Additionally, we refer readers to section IX.F.9. of this proposed rule for discussion of a similar policy to adopt this measure in the Medicare Promoting Interoperability Program.

We invite public comment on our proposal to adopt the Hospital Harm—Postoperative VTE eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination.

#### 4. Proposed Removals in the Hospital Inpatient Quality Reporting Program Measure Set

We are proposing to remove three measures from the Hospital Inpatient Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 payment determination: (1) Venous Thromboembolism Prophylaxis eCQM; (2) Intensive Care Unit Venous Thromboembolism Prophylaxis eCQM; and (3) Discharged on Antithrombotic Therapy eCQM. We provide more details on each of these proposals in the subsequent section.

##### a. Proposed Removal of Two Venous Thromboembolism Electronic Clinical Quality Measures

We refer readers to the FY 2014 IPPS/LTCH PPS final rule where we adopted the Venous Thromboembolism Prophylaxis (VTE-1) and Intensive Care Unit Venous Thromboembolism Prophylaxis (VTE-2) eCQMs beginning with the CY 2014 reporting period/FY 2016 payment determination (78 FR 50807 through 50810). These measures were originally adopted as chart-abstracted measures and were later specified as eCQMs, which we adopted as optional measures for hospitals to self-select. We propose to remove the VTE-1 and VTE-2 eCQMs from the Hospital Inpatient Quality Reporting Program, beginning with the CY 2028 reporting period/FY 2030 payment determination, under our measure removal factor 5, the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic, as described at 42 CFR 412.140(g)(3)(i)(E), if the proposed Hospital Harm—Postoperative VTE

<sup>322</sup> Lawson, E.H., Hall, B.L., Louie, R., Ettner, S. L., Zingmond, D.S., Han, L., Rapp, M., & Ko, C.Y. (2013). Association Between Occurrence of a Postoperative Complication and Readmission: Implications for Quality Improvement and Cost Savings. *Annals of Surgery*, 258(1), 10–18. Available at: <https://doi.org/10.1097/sla.0b013e31828e3ac3>.

<sup>323</sup> Brooke, B. S., Goodney, P. P., Kraiss, L. W., Gottlieb, D. J., Samore, M. H., Finlayson, S. R. G. (2015). Readmission destination and risk of mortality after major surgery: an observational cohort study. In *The Lancet* (Vol. 386, pp. 884–895). Available at: [http://dx.doi.org/10.1016/S0140-6736\(15\)60087-3](http://dx.doi.org/10.1016/S0140-6736(15)60087-3).

<sup>324</sup> Partnership for Quality Measurement. (February 2026). Fall 2025 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute and Chronic Events. This report will be published in the spring 2026 and will be available at: <https://p4qm.org/em/news-events>. <https://p4qm.org/em/news-events>.

<sup>325</sup> To access the value sets for the measure, please visit the Value Set Authority Center, sponsored by the National Library of Medicine, at <https://vsac.nlm.nih.gov/>.



eCQM is adopted.<sup>326</sup> The VTE–1 eCQM assesses the proportion of patients admitted to the hospital who received VTE prophylaxis or have documentation of why no VTE prophylaxis was given between the day of hospital admission to the day after admission or surgery end date. The VTE–2 eCQM measures the proportion of patients admitted or transferred to the intensive care unit (ICU) who received VTE prophylaxis or have documentation of why no VTE prophylaxis was given between the day of admission or transfer to the ICU to the day after admission or surgery end date.

Patient safety topics such as appropriate VTE prophylaxis continue to be high priority topics for quality measurement in the hospital inpatient setting. Since introducing the VTE–1 and VTE–2 eCQMs into the Hospital Inpatient Quality Reporting Program over a decade ago, we have developed an outcome-focused VTE eCQM, Hospital Harm—Postoperative VTE eCQM, as proposed for adoption in section IX.C.3.b. of this proposed rule beginning with the FY 2030 payment determination. The Hospital Harm—Postoperative VTE eCQM is an outcome measure that builds upon the existing process measures and evaluates the incidence of postoperative VTE events, assessing the success of the VTE prophylaxis strategies measured by the VTE–1 and VTE–2 eCQMs, and thus is more strongly associated with desired patient outcomes for this particular topic. It also aligns with our efforts to reduce burden and refine the Hospital Inpatient Quality Reporting Program's measure set by replacing two process measures with a single outcome measure. In addition, the VTE–1 and VTE–2 eCQMs were retired from The Joint Commission's ORYX® requirements effective CY 2026.<sup>327 328</sup>

<sup>326</sup> We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital Inpatient Quality Reporting Program's removal factors. Removal factors are codified at 42 CFR 412.140(g)(2) and (3).

<sup>327</sup> The Joint Commission. (Oct. 2025). 2026 ORYX Performance Measurement Reporting Requirements. Available at: <https://jointcommission-ddsp.atlassian.net/wiki/spaces/DCS/pages/1030619137/2026+ORYX+Performance+Measurement+Reporting+Requirements>.

<sup>328</sup> The ORYX initiative integrates performance measurement data into The Joint Commission's standards-based survey and accreditation process to support hospitals in their quality improvement

We note that the proposed removal of the VTE–1 and VTE–2 eCQMs is contingent upon our finalizing the proposal to adopt the Hospital Harm—Postoperative VTE eCQM as discussed in section IX.C.3.b. of this proposed rule.

We note that we are also proposing to remove the VTE–1 and VTE–2 eCQMs in the Medicare Promoting Interoperability Program beginning with the CY 2028 reporting period. For more information, we refer readers to section IX.F.9. of this proposed rule.

We invite public comment on our proposal to remove the VTE–1 and VTE–2 eCQMs beginning with the CY 2028 reporting period/FY 2030 payment determination.

#### b. Proposed Removal of the Discharged on Antithrombotic Therapy Electronic Clinical Quality Measure Beginning With the FY 2030 Payment Determination

We refer readers to the FY 2014 IPPS/LTCH PPS final rule where we adopted the Discharged on Antithrombotic Therapy (STK–02) eCQM into the Hospital Inpatient Quality Reporting Program eCQM measure set for self-selected reporting beginning with the CY 2014 reporting period (78 FR 50807 through 50810).<sup>329</sup> This measure was originally adopted as a hart-abstracted measure and was later specified as an eCQM, which we adopted as an option for hospitals to self-select (76 FR 51633 through 51634 and 78 FR 50807 through 50810).<sup>330</sup> The STK–02 eCQM assesses the proportion of patients hospitalized with ischemic stroke who are prescribed or continue antithrombotic therapy at the time of hospital discharge. We propose to remove the STK–02 eCQM from the Hospital Inpatient Quality Reporting Program, beginning with the CY 2028 reporting period/FY 2030 payment determination under measure removal factor 1, measure performance among hospitals is so high and unvarying that meaningful distinctions

efforts through the continuous monitoring and evaluation. For more details on The Joint Commission's accreditation, we refer readers to: <https://www.jointcommission.org/en-us/accreditation/performance-measurement>.

<sup>329</sup> Partnership for Quality Measurement. STK–02: Discharged on Antithrombotic Therapy. Available at: <https://p4qm.org/measures/0435e>.

<sup>330</sup> For more details on STK–02 specifications, we refer readers to the eCQI Resource Center available at: (<https://ecqi.healthit.gov/eh-cah>).

and improvements in performance can no longer be made, as described at 42 CFR 412.140(g)(3)(i)(A).<sup>331</sup>

Over four of the most recent reporting periods, hospital performance has been so high and unvarying that it meets our criteria for “topped out” under measure removal factor 1 (83 FR 41540 through 41544), that is, statistically indistinguishable performance at the 75th and 90th percentiles, and truncated coefficient of variation  $\leq 0.10$ , see Table IX.C.2. Since the STK–02 eCQM is a self-selected eCQM, meaning that not all hospitals are required to report it, we considered that the topped out status may not reflect national performance. However, the number of hospitals reporting on this measure has remained consistently high, with approximately two-thirds of the Hospital Inpatient Quality Reporting Program-eligible hospitals reporting since FY 2023. We therefore believe that the measure results represent most hospitals' performance on this measure. Further, the CBE recently selected this measure for review for potential removal from the Hospital Inpatient Quality Reporting Program as part of the Measure Set Review process and ultimately recommended its discontinuation due to minimal variation and stable median performance across hospitals.<sup>332</sup> The STK–02 eCQM was also retired from The Joint Commission's ORYX® requirements effective CY 2026.<sup>333 334</sup>

<sup>331</sup> We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital Inpatient Quality Reporting Program's removal factors. Removal factors are codified at 42 CFR 412.140(g)(2) and (3) (88 FR 59144).

<sup>332</sup> Partnership for Quality Measurement (2025). 2025 Measure Set Review Draft Meeting Summary. Available at: <https://p4qm.org/sites/default/files/2025-11/Del-4-11-2025-MSR-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

<sup>333</sup> The Joint Commission. (Oct. 2025). 2026 ORYX Performance Measurement Reporting Requirements. Available at: <https://jointcommission-ddsp.atlassian.net/wiki/spaces/DCS/pages/1030619137/2026+ORYX+Performance+Measurement+Reporting+Requirements>.

<sup>334</sup> The ORYX initiative integrates performance measurement data into The Joint Commission's standards-based survey and accreditation process to support hospitals in their quality improvement efforts through the continuous monitoring and evaluation. For more details on The Joint Commission's accreditation, we refer readers to: <https://www.jointcommission.org/en-us/accreditation/performance-measurement>.



**TABLE IX.C.2.: STK-02 DATA FROM REPORTING HOSPITALS  
Q1 2020 THROUGH Q4 2024**

| Payment Determination | Performance Period | Mean  | 75th Percentile | 90th Percentile | Truncated COV |
|-----------------------|--------------------|-------|-----------------|-----------------|---------------|
| FY 2023               | Q1 2021- Q4 2021   | 91.66 | 100.00          | 100.00          | 0.055         |
| FY 2024               | Q1 2022- Q4 2022   | 92.26 | 99.00           | 100.00          | 0.045         |
| FY 2025               | Q1 2023- Q4 2023   | 92.71 | 99.00           | 100.00          | 0.038         |
| FY 2026               | Q1 2024- Q4 2024   | 93.13 | 99.00           | 100.00          | 0.034         |

Stroke has been and remains a priority topic for quality measurement in the hospital inpatient setting for over a decade due to its high prevalence and substantial impact on quality of life, disability, and death (76 FR 51633 through 51634).<sup>335</sup> If the STK-02 eCQM measure is removed from the Hospital Inpatient Quality Reporting Program, we will continue to address quality of care for stroke patients through the use of other clinical outcome measures. These measures include the Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Acute Ischemic Stroke (MORT-30-STK) measure, which assesses the hospital-level, risk-standardized mortality rate after hospital admission for acute ischemic stroke (78 FR 50798 through 50802, most recently modified at 90 FR 36997 through 37001) as well as the remaining two eQMs that are a part of the stroke measure set, including the Anticoagulation Therapy for Atrial Fibrillation (STK-03) eCQM and the Antithrombotic Therapy by the End of Hospital Day Two (STK-05) eCQM (76 FR 51633 through 51634, 78 FR 50807 through 50810).

We note that we are also proposing to remove the STK-02 eCQM in the Medicare Promoting Interoperability Program beginning with the CY 2028 reporting period. For more information, we refer readers to section IX.F.9. of this proposed rule.

We invite public comment on our proposal to remove the STK-02 eCQM beginning with CY 2028 reporting period/FY 2030 payment determination.

#### 5. Proposed Modifications to Current Measures in the Hospital Inpatient Quality Reporting Program Measure Set

We propose modifications to three measures that are currently in the Hospital Inpatient Quality Reporting Program measure set beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination: (1) Excess Days in Acute Care after

Hospitalization for Acute Myocardial Infarction measure; (2) Excess Days in Acute Care after Hospitalization for Heart Failure measure; and (3) Excess Days in Acute Care after Hospitalization for Pneumonia measure.

#### a. Proposed Modifications to Three Excess Days in Acute Care Measures

##### (1) Background

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49690), we began including excess days in acute care quality measures in the Hospital Inpatient Quality Reporting Program to capture the quality of care transitions provided to discharged patients. The previously finalized EDAC measures are summarized:

- Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI EDAC) measure (adopted at 80 FR 49680 through 49690; modified at 87 FR 49269 through 49272).
- Excess Days in Acute Care after Hospitalization for Heart Failure (Heart Failure EDAC) measure (adopted at 80 FR 49682 through 49690).
- Excess Days in Acute Care after Hospitalization for Pneumonia (Pneumonia EDAC) (adopted at 81 FR 57142 through 57148).

For more details on these EDAC measures, we refer readers to the EDAC measures updates and specifications reports available at: <https://qualitynet.cms.gov/inpatient/measures/edac>.

Since adoption into the Hospital Inpatient Quality Reporting Program, these EDAC measures have contributed to our assessment of care coordination and patient outcomes, providing a broader view of quality of care than can be captured by individual process-of-care measures. Safely transitioning patients from hospital to home requires a complex series of tasks which would be cumbersome to capture individually as process measures: timely and effective communication between providers, prevention of and response to complications, patient education about post-discharge care and self-management, timely follow-up, and

more.<sup>336 337</sup> Suboptimal transitions contribute to a variety of adverse events post-discharge that result in patients returning to the hospital.<sup>338</sup> When these EDAC measures were adopted into the Hospital Inpatient Quality Reporting Program measure set, they only included Medicare Fee-For-Service beneficiaries in the measure cohorts. Since the initial adoption of these measures, the proportion of Medicare Advantage beneficiaries has increased from 35 percent of the Medicare population to over 50 percent.<sup>339</sup> Omitting Medicare Advantage beneficiaries from quality reporting leaves a critical gap in assessing acute events, care transitions, and avoidable acute utilization among a large population of Medicare beneficiaries. Capturing care transition outcomes for all Medicare beneficiaries for these acute conditions continues to be a high priority for CMS. We note that returns to the ED, observation stays, or unplanned readmissions are disruptive to patients and caregivers, costly to the healthcare system, and put patients at additional risk of hospital-acquired infections and complications.<sup>340</sup> Therefore, we propose to adopt modifications to the AMI, Heart Failure, and Pneumonia EDAC measures

<sup>336</sup> Tyler, N., Hodkinson, A., Planner, C., Angelakis, I., Keyworth, C., Hall, A., Panagioti, M. (2023). Transitional care interventions from hospital to community to reduce health care use and improve patient outcomes: A systematic review and network meta-analysis. *JAMA Network Open*, 6(11), e2344825. Available at: <https://doi.org/10.1001/jamanetworkopen.2023.44825>.

<sup>337</sup> Balasubramanian, I., Andres, E. B., & Malhotra, C. (2025). Outpatient Follow-Up and 30-Day Readmissions: A Systematic Review and Meta-Analysis. *JAMA Network Open*, 8(11), e2541272–e2541272. Available at: <https://doi.org/10.1001/jamanetworkopen.2025.41272>.

<sup>338</sup> Tyler, N., Hodkinson, A., Planner, C., Angelakis, I., Keyworth, C., Hall, A., Panagioti, M. (2023). Transitional care interventions from hospital to community to reduce health care use and improve patient outcomes: A systematic review and network meta-analysis. *JAMA Network Open*, 6(11), e2344825. Available at: <https://doi.org/10.1001/jamanetworkopen.2023.44825>.

<sup>339</sup> Centers for Medicare & Medicaid Services. (2025). Medicare Enrollment Dashboard. Available at: <https://data.cms.gov/tools/medicare-enrollment-dashboard>.

<sup>340</sup> CMS QualityNet. Excess Days in Acute Care (EDAC) Measures Overview. Available at: <https://qualitynet.cms.gov/inpatient/measures/edac>.

<sup>335</sup> Department of Health and Human Services. Heart Disease and Stroke. Available at: <https://odphp.health.gov/healthypeople/objectives-and-data/browse-objectives/heart-disease-and-stroke>.

beginning with the July 1, 2024 through June 30, 2026 performance period, which is associated with the FY 2028 payment determination. We also refer readers to section IX.C.3.a. of this FY 2027 IPPS/LTCH PPS proposed rule where we propose to add the Diabetes EDAC measure into the Hospital Inpatient Quality Reporting Program.

## (2) Overview of Proposed Updates to Measures

We propose to modify the AMI, Heart Failure, and Pneumonia EDAC measures

with two substantive updates: (1) expand the measure inclusion criteria to include Medicare Advantage beneficiaries; and (2) shorten the performance period from 3 years to 2 years. Inclusion of Medicare Advantage beneficiaries expands quality measurement of care coordination outcomes across all Medicare beneficiaries, enhances the reliability of the measure scores, leads to more hospitals receiving results, and increases the chance of identifying meaningful differences in quality for

some low-volume hospitals. Based on our analysis that included Medicare Advantage beneficiaries in addition to the Medicare Fee-For-Service measure cohort, we found that the measures could achieve a satisfactory level of reliability with a 2-year reporting period. Table IX.C.3. summarizes the reliability scores for the three modified EDAC measures for the CY 2022 through CY 2023 reporting period with the inclusion of Medicare Advantage beneficiaries:<sup>341</sup>

**TABLE IX.C.3 EDAC MEASURES RELIABILITY ESTIMATES USING A 2-YEAR REPORTING PERIOD**

| Measure            | Mean (SD)     | Range       | 25 <sup>th</sup> Percentile | 50 <sup>th</sup> Percentile | 75 <sup>th</sup> Percentile |
|--------------------|---------------|-------------|-----------------------------|-----------------------------|-----------------------------|
| AMI EDAC           | 0.922 (0.049) | 0.786-0.992 | 0.897                       | 0.935                       | 0.960                       |
| Heart Failure EDAC | 0.863 (0.128) | 0.542-0.996 | 0.793                       | 0.92                        | 0.962                       |
| Pneumonia EDAC     | 0.873 (0.109) | 0.593-0.996 | 0.806                       | 0.920                       | 0.960                       |

The mean reliability for each of the EDAC measures exceeds the CBE established minimum of 0.6.<sup>342</sup> We therefore propose to shorten the reporting period from 3 to 2 years for the modified EDAC measures in order to provide hospitals, consumers, and other members of the public with more recent measure information.

These measures capture the quality of care transitions provided to discharged patients hospitalized with AMI, heart failure, or pneumonia by collectively measuring different types of returns to the hospital (ED visit, observation stay, or readmission), which are all adverse acute care outcomes that can occur post-discharge. With the increase in Medicare Advantage beneficiaries to over half of all Medicare beneficiaries, these modifications would better reflect overall patient care coordination among a broader population of patients, improving measure reliability. Shortening the reporting period would allow measure results to reflect more recent hospital performance and provide more actionable insights for quality improvement.

## (3) Measure Calculation

The modified AMI, Heart Failure, and Pneumonia EDAC measures would

continue to assess the number of days the patient spends in acute care within 30 days post-discharge from an inpatient hospitalization with a principal diagnosis of AMI, heart failure, or pneumonia. The measures adjust for factors including patient age, comorbid diseases, and indicators of patient frailty.<sup>343</sup> The hospital-level 30-day all-cause EDAC for each measure is a risk adjusted calculation using a random-effects binomial model which calculates the difference, or excess days, between a hospital's predicted days (the average number of days a patient spent in acute care after adjusting for the risk factors) and expected days (the average number of risk adjusted days in acute care a patient would have been expected to spend if discharged from an average-performing hospital with the same case mix) per 100 discharges. Unplanned readmissions are defined using the planned readmission algorithm.<sup>344</sup>

### (a) Numerator

The numerator of the measure is a count of the number of days the patient spends in acute care within 30 days of discharge from an eligible index hospitalization for AMI, heart failure, or pneumonia. We define days in acute care as days spent in an ED, an

observation stay, or admitted as an unplanned readmission for any cause to a short-term acute care hospital, within 30 days from the date of discharge from the index hospitalization. ED visits are counted as one whole day, regardless of how many hours the patient spends in the ED or whether the ED visit crosses more than one calendar date. Observation stays are counted by hours and rounded up to the nearest whole day.<sup>345</sup>

### (b) Denominator

To be included in the measure cohort, patients must meet the following inclusion criteria:

- Have a principal discharge diagnosis of AMI, heart failure, or pneumonia;
- Enrolled in Medicare Fee-For-Service Part A and Part B or Medicare Advantage for 12-months prior to the date of admission and enrolled in Part A or Medicare Advantage during the index admission;<sup>346</sup>
- Aged 65 or older;
- Discharged alive from a non-federal short-term acute care hospital or Veterans Health Administration hospital; and
- Not transferred to another acute care facility.

<sup>341</sup> 2024 Excess Days in Acute Care Measures Updates and Specifications Report. Available at: <https://www.p4qm.org/prmr-measures/muc2025-030>.

<sup>342</sup> For more details on reliability guidance, we refer readers to the Reliability Guidance for the Endorsement and Maintenance of Clinical Quality Measures Document. Available at: <https://p4qm.org/em/resources>.

<sup>343</sup> QualityNet. Excess Days in Acute Care Measures Methodology. Available at: <https://qualitynet.cms.gov/inpatient/measures/edac/methodology>.

[qualitynet.cms.gov/inpatient/measures/edac/methodology](https://qualitynet.cms.gov/inpatient/measures/edac/methodology).

<sup>344</sup> Details regarding the planned readmission algorithm can be found in a zip file on the CMS Measure Methodology site, available at: <https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/measure-methodology>.

<sup>345</sup> QualityNet. Excess Days in Acute Care Measures Methodology. Available at: <https://qualitynet.cms.gov/inpatient/measures/edac/methodology>.

<sup>346</sup> This requirement is not applicable to Veterans Health Administration (VHA) beneficiaries hospitalized in VHA hospitals, who are eligible for inclusion in the cohort regardless of their Medicare enrollment status. VHA beneficiaries hospitalized in non-VHA hospitals must be concurrently enrolled in Medicare Fee-For-Service Part A or Medicare Advantage at the time of the index admission to be eligible for cohort inclusion.

For more detailed measure specifications, including denominator exclusions for each condition, we refer readers to the EDAC measure methodology reports available at: <https://qualitynet.cms.gov/inpatient/measures/edac/methodology>.

#### (4) Pre-Rulemaking Process and Measure Endorsement

##### (a) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement website for details on the Pre-rulemaking Measure Review process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.<sup>347 348</sup> The Pre-rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and the Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available “2025 Measures Under Consideration List,” including the AMI EDAC (MUC2025–030), Heart Failure EDAC (MUC2025–031), and Pneumonia EDAC (MUC2025–039) measures.<sup>349</sup>

The voting results of the Recommendation Group for the proposed modifications to the AMI EDAC measure were: 18 members (86 percent) recommended adopting the measure into the Hospital Inpatient Quality Reporting Program; three members (14 percent) voted not to recommend the measure for adoption. The voting results for the proposed modifications to the Heart Failure EDAC measure were: 19 members (90 percent) recommended adopting the measure into the Hospital Inpatient Quality Reporting Program; two members (10 percent) voted not to recommend the measure for adoption. The voting results for the proposed modifications to the Pneumonia EDAC measure were: 19 members (90 percent) recommended adopting the measure into the Hospital Inpatient Quality Reporting Program;

two members (10 percent) voted not to recommend the measure for the adoption. Thus, the Recommendation Group reached consensus agreement to recommend the AMI EDAC, Heart Failure EDAC, and Pneumonia EDAC measures for use in the Hospital Inpatient Quality Reporting Program.<sup>350</sup>

Overall, the Recommendation Group supported the addition of Medicare Advantage beneficiaries and the reduction of the performance period from 3 years to 2 years, noting these changes improved the comprehensiveness and timeliness of reporting. The Recommendation Group members who recommended these measures suggested adding risk adjustment factors for medically underserved and rural areas, where limited access to post-acute services may affect readmissions beyond a hospital’s control. Recommendation Group members who voted not to recommend adoption of the measure for the Program provided the following rationales: (1) concerns that the 30-day post-discharge window may not be appropriate; and (2) concerns regarding AMI EDAC measure’s complexity, diagnosis set, and the risk adjustment approach.

Regarding the suggestion to add additional risk adjustment factors, in alignment with other readmission measures, we do not adjust the EDAC measures for rurality or medically underserved populations. We note that Critical Access Hospitals (CAHs), which serve higher proportions of rural and medically underserved populations, are not required to report to the Hospital Inpatient Quality Reporting Program.<sup>351</sup> We also note that EDAC measures are risk-standardized for patient demographics and comorbidities, which helps account for varying health complexities. Further, we would continue to provide hospitals with patient-level information to help inform quality improvement efforts that can be targeted to specific patient populations. We would continue to monitor the measures’ performance as part of our routine monitoring and evaluation efforts to identify potential unintended consequences.

We note that the 30-day timeframe is consistent with the existing measure specifications that have been endorsed by a CBE and publicly reported. In

addition, the EDAC measures were originally designed to complement condition specific 30-day readmission measures for the same conditions and therefore the 30-day outcome window is aligned. The 30-day timeframe allows for a more complete reflection of the hospital’s discharge plan which includes follow-up, care coordination, and patient self-management education.

Regarding the AMI EDAC measure specifically, Recommendation Group members expressed concerns regarding its complexity and relatively narrow diagnosis set, noting a preference for other metrics to assess AMI care. While statistically complex, the AMI EDAC risk-model was determined by the CBE to indicate an effective model discrimination for a readmission-type measure with a c-statistic<sup>352</sup> of 0.68, and predictive ability<sup>353</sup> of 1.4 percent to 10.1 percent. Further, the measure developer considered threats to validity during measure development and testing of a risk adjustment model. The measure is risk adjusted for patient functional status (frailty indicator), patient-level demographics (age), and patient-level health status and clinical conditions (case-mix adjustment, comorbidities, and severity of illness). The results of model discrimination testing and calibration using the c-statistic and examining predictive ability suggest that the model effectively differentiates excess days in acute care after hospitalization for heart failure levels and adequately adjusts for differences in patient characteristics.<sup>354</sup>

Recommendation Group members highlighted potential shortcomings in the current risk adjustment approach for the AMI EDAC measure, particularly the

<sup>352</sup> The c-statistic is an indicator of the model’s discriminant ability or ability to correctly classify those patients who have and have not had a qualifying event within 30 days. Potential values range from 0.5, meaning no better than chance, to 1.0, an indication of perfect prediction. The CBE has determined that for readmission-type measures, a c-statistic of 0.68 is considered an effective model of discriminant ability. We refer readers to the “2024 Excess Days in Acute Care Measures Updates and Specifications Report,” available at: <https://www.p4qm.org/prmr-measures/muc2025-030> for more details.

<sup>353</sup> Predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects. A model with good predictive ability would see a wide range in observed outcomes between lowest and highest deciles of predicted outcomes. We have calculated the range of mean observed hospital ratios between the lowest and highest deciles of hospital visit probabilities. We refer readers to the “2024 Excess Days in Acute Care Measures Updates and Specifications Report,” available at: <https://www.p4qm.org/prmr-measures/muc2025-030> for more details.

<sup>354</sup> PQM. 2025 Pre-Rulemaking Measure Review Preliminary Assessment: AMI EDAC. Available at: <https://www.p4qm.org/sites/default/files/2025-12/MUC2025-030-PA.pdf>.

<sup>347</sup> Partnership for Quality Management. Pre-Rulemaking Measure Review web page. Available at: <https://p4qm.org/prmr/about>.

<sup>348</sup> We note the Pre-Rulemaking Measure Review voting process was updated in 2025. We refer readers to the corresponding footnote in section IX.C.3.a.(4).(a). of this proposed rule for details on the updated Pre-Rulemaking Measure Review voting process.

<sup>349</sup> Centers for Medicare & Medicaid Services. (2025). 2025 Measures Under Consideration List. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview>.

<sup>350</sup> Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendations Report. Available at: <https://p4qm.org/prmr/news-events>.

<sup>351</sup> CMS. Critical Access Hospitals. Available at: <https://www.cms.gov/medicare/health-safety-standards/certification-compliance/critical-access-hospitals>.

comorbidity adjustment for non-ST-segment elevation myocardial infarction (NSTEMI) cases. The measure developer used an empirical approach for the selection of risk variables included in adjustments for hospital-level case mix. The index and history (pre-index) codes were selected based on their prevalence and the index and pre-index variables were combined based on their correlation with each other and their associations with the outcome. For AMI EDAC, ST-segment elevation myocardial infarction (STEMI) involving the right and left coronary arteries occurring in the 12 months prior to the index admission were identified as risk adjustment variables, while NSTEMI was not identified. Clinically, STEMI presents a more severe form of myocardial infarction for which aggressive interventions are required in a short period of time. Additionally, we wish to emphasize we have conducted extensive evaluation of the proposed updated risk adjustment methodology and the updated risk methodology shows significant improvements from the previous model. We refer readers to Table IX.C.4., in section IX.C.5.a.(6)., for more details on the technical updates to the risk adjustment methodology for the three modified EDAC measures.

After taking these recommendations and concerns into consideration, we propose to modify the three EDAC measures in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination.

#### (b) Measure Endorsements

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The Heart Failure EDAC (CBE #2880) and Pneumonia EDAC (CBE #2882) measures were last endorsed in the Spring 2021 CBE review cycle and are planned for maintenance review in the Fall 2027 cycle.<sup>355 356</sup> The updated

AMI EDAC (CBE #2881) measure, which included the addition of Medicare Advantage beneficiaries, was most recently submitted to the CBE's Endorsement and Maintenance Cost and Efficiency Committee in the Spring 2025 review cycle. The Endorsement and Maintenance Cost and Efficiency Committee voted to endorse the AMI EDAC measure with conditions. The condition imposed was for the measure developer to empirically explore the differences with outpatient visits and post-hospitalizations for Medicare Advantage beneficiaries compared to Fee-For-Service beneficiaries when the measure returns in five years for maintenance endorsement in the Spring 2030 cycle.<sup>357 358</sup>

#### (5) Data Source, Submission, and Public Reporting

The modified EDAC measures would be calculated using administrative data from Medicare Fee-For-Service claims or Medicare Advantage encounters, or both. This data is routinely generated by hospitals and submitted to CMS for all Medicare beneficiaries, which includes Medicare Advantage and Medicare Fee-For-Service beneficiaries. Therefore, a hospital would not be required to report any additional data for this measure. Enrollment status would be obtained from the Medicare Enrollment Database which contains beneficiary demographic, benefit/coverage, and vital status information. The proposed modified EDAC measures would be calculated and publicly reported on an annual basis using 24 months of prior data for the measurement period. We would then publicly report the measures results on the Compare tool, currently available at: <https://www.medicare.gov/care-compare/>, or successor CMS website.

We invite public comment on our proposal to modify the AMI, Heart

Failure and Pneumonia EDAC measures to include Medicare Advantage patients in the measure cohort and reduce the performance period from 3 years to 2 years, beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination.

#### (6) Technical Updates

We are also notifying the public of technical updates to the three EDAC measures' risk adjustment methodology in the Hospital Inpatient Quality Reporting Program, beginning with the FY 2028 payment determination, to use individual International Classification of Diseases, Tenth Revision (ICD-10) codes to improve the measure's risk adjustment methodology. The risk adjustment strategy currently in use involves grouping ICD-10 diagnosis codes from the CMS Hierarchical Condition Categories (HCC) system into clinically relevant categories.<sup>359</sup> We recently notified hospitals of the same technical update to our risk adjustment model to use individual ICD-10 codes instead of HCCs for two measures—MORT-30-STK and COMP-HIP-KNEE—in the Hospital Inpatient Quality Reporting Program to better leverage the data and analytical advances since these measures were initially developed (90 FR 36997 through 37008). With this new approach, the ability of the risk adjustment model to account for condition-specific risk improved. See Table IX.C.4. for a summary of improvements to the risk adjustment model performance for the three modified EDAC measures in the Hospital Inpatient Quality Reporting Program.<sup>360 361</sup>

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<sup>359</sup> QualityNet. 2025 Condition-Specific Excess Days in Acute Care Measures Updates and Specifications Report: AMI, HF, and Pneumonia. Available at: <https://qualitynet.cms.gov/inpatient/measures/edac/methodology>.

<sup>360</sup> 2024 Excess Days in Acute Care Measures Updates and Specifications Report. Available at: <https://www.p4qm.org/prmr-measures/muc2025-030>.

<sup>361</sup> QualityNet. 2025 Condition-Specific Excess Days in Acute Care Measures Updates and Specifications Report: AMI, HF, and Pneumonia. Available at: <https://qualitynet.cms.gov/inpatient/measures/edac/methodology>.

<sup>355</sup> Batelle. PQM. Excess days in acute care (EDAC) after hospitalization for pneumonia. Available at: <https://www.p4qm.org/measures/2882>.

<sup>356</sup> Batelle. PQM. Excess days in acute care (EDAC) after hospitalization for heart failure (HF). Available at: <https://www.p4qm.org/measures/2880>.

<sup>357</sup> Battelle. Excess days in acute care (EDAC) after hospitalization for acute myocardial infarction (AMI). Available at: <https://www.p4qm.org/measures/2881>.

<sup>358</sup> Battelle. (November 2025). Draft Spring 2025 Cycle Endorsement and Maintenance Technical Report: Cost and Efficiency. Available at: <https://p4qm.org/sites/default/files/Cost%20and%20Efficiency/material/Cost-Efficiency-Spring-2025-Technical-Report.pdf>.

TABLE IX.C.4. EDAC MEASURES RISK ADJUSTMENT MODEL PERFORMANCE COMPARISON

| Measure Title      | Fee-For-Service-only cohort with HCC-based Risk Variables (July 1, 2022 through June 30, 2023) | Fee-For-Service and Medicare Advantage cohort with ICD-10-based Risk Variables (January 1, 2022 through December 30, 2023) |
|--------------------|------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
|                    | C-Statistic (predictive ability)                                                               | C-Statistic (predictive ability)                                                                                           |
| AMI EDAC           | 0.60 (85 - 123)                                                                                | 0.68 (59 - 261)                                                                                                            |
| Heart Failure EDAC | 0.59 (133 - 172)                                                                               | 0.64 (89 - 361)                                                                                                            |
| Pneumonia EDAC     | 0.61 (106 - 152)                                                                               | 0.67 (59 - 338)                                                                                                            |

Note: The predictive ability is the range of mean observed days in acute care per 100 discharges between the lowest and highest predicted deciles.

6. Summary of Previously Finalized and Proposed Hospital Inpatient Quality Reporting Program Measures

This table IX.C.5. summarizes the previously finalized and newly proposed Hospital Inpatient Quality Reporting Program measures for the FY

2028 to FY 2031 payment determinations, which would remove the STK–02, VTE–1, and VTE–2 eCQMs discussed in section IX.C.4. of this proposed rule; modify three EDAC measures as discussed in section IX.C.5. of this proposed rule; add the Diabetes

EDAC measure and the Hospital Harm—Postoperative VTE eCQM as discussed in section IX.C.3. in this proposed rule; and add the Advance Care Planning eCQM and five mortality measures as discussed in section IX.B.1. and IX.B.2. of this proposed rule:

**TABLE IX.C.5.: PREVIOUSLY FINALIZED AND PROPOSED HOSPITAL  
INPATIENT QUALITY REPORTING PROGRAM MEASURE SET BY DATA  
COLLECTION METHOD AND PAYMENT DETERMINATION (PD)**

| Measure Name                                                                                                                                         | CBE Number  | FY 2023 PD            | FY 2029 PD            | FY 2030 PD | FY 2031 PD           |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-----------------------|-----------------------|------------|----------------------|
| <b>Patient Experience of Care Survey Measures</b>                                                                                                    |             |                       |                       |            |                      |
| Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)                                          | 0166 (0228) | ✓                     | ✓                     | ✓          | ✓                    |
| <b>Chart-Abstracted Clinical Process of Care Measures</b>                                                                                            |             |                       |                       |            |                      |
| Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)                                                                                | 0500        | ✓                     | ✓                     | ✓          | ✓                    |
| <b>Structural Measures</b>                                                                                                                           |             |                       |                       |            |                      |
| Maternal Morbidity Structural Measure                                                                                                                | N/A         | ✓                     | ✓                     | ✓          | ✓                    |
| Patient Safety Structural Measure                                                                                                                    | N/A         | ✓                     | ✓                     | ✓          | ✓                    |
| Age Friendly Hospital Measure                                                                                                                        | N/A         | ✓                     | ✓                     | ✓          | ✓                    |
| <b>Claims-Based Patient Safety Measures</b>                                                                                                          |             |                       |                       |            |                      |
| Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Inpatient Surgical Complications Rate)                         | 4125        | ✓                     | ✓                     | ✓          | ✓                    |
| <b>Claims-Based Mortality/Complications Measures</b>                                                                                                 |             |                       |                       |            |                      |
| Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke                                                        | N/A         | ✓                     | ✓                     | ✓          | ✓                    |
| Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA                                                  | 1550        | ✓                     | ✓                     |            |                      |
| Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization (MORT-30-AMI)**                   | 0230        | Proposed for Adoption | ✓                     | ✓          | Proposed for Removal |
| Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (MORT-30-HF)**                                  | 0229        | Proposed for Adoption | ✓                     | ✓          | Proposed for Removal |
| Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT-30-PN)**                                      | 0468        | Proposed for Adoption | ✓                     | ✓          | Proposed for Removal |
| Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT-30-COPD)** | 1893        | Proposed for Adoption | ✓                     | ✓          | Proposed for Removal |
| Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT-30-CABG) measures**         | 2558        | Proposed for Adoption | ✓                     | ✓          | Proposed for Removal |
| <b>Claims-Based Coordination of Care Measures</b>                                                                                                    |             |                       |                       |            |                      |
| Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction***                                                                   | 2881        | ✓                     | ✓                     | ✓          | ✓                    |
| Excess Days in Acute Care after Hospitalization for Heart Failure***                                                                                 | 2880        | ✓                     | ✓                     | ✓          | ✓                    |
| Excess Days in Acute Care after Hospitalization for Pneumonia***                                                                                     | 2882        | ✓                     | ✓                     | ✓          | ✓                    |
| Excess Days in Acute Care after Hospitalization for Diabetes****                                                                                     | N/A         |                       | Proposed for Adoption | ✓          | ✓                    |
| <b>National Healthcare Safety Network Measures</b>                                                                                                   |             |                       |                       |            |                      |
| HCP Influenza Vaccination                                                                                                                            | 0431        | ✓                     | ✓                     | ✓          | ✓                    |
| Catheter- Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations                                  | 0138        | ✓                     | ✓                     | ✓          | ✓                    |
| Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations                                | 0139        | ✓                     | ✓                     | ✓          | ✓                    |

| Measure Name                                                                                                                        | CBE Number | FY 2028 PD | FY 2029 PD | FY 2030 PD                           | FY 2031 PD |
|-------------------------------------------------------------------------------------------------------------------------------------|------------|------------|------------|--------------------------------------|------------|
| <b>Claims and Electronic Data Measures</b>                                                                                          |            |            |            |                                      |            |
| Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)                                                            | 3502e      | ✓          | ✓          | ✓                                    | ✓          |
| Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)                                                                            | 2879e      | ✓          | ✓          | ✓                                    | ✓          |
| <b>Patient-Reported Outcome Performance Measures</b>                                                                                |            |            |            |                                      |            |
| Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)    | 3559       | ✓          | ✓          | ✓                                    | ✓          |
| <b>Electronic Clinical Quality Measures</b>                                                                                         |            |            |            |                                      |            |
| Discharged on Antithrombotic Therapy*****                                                                                           | 0435e      | ✓*         | ✓*         | Proposed for Removal                 |            |
| Anticoagulation Therapy for Atrial Fibrillation/Flutter                                                                             | 0436e      | ✓*         | ✓*         | ✓*                                   | ✓*         |
| Antithrombotic Therapy by the End of Hospital Day Two                                                                               | 0438e      | ✓*         | ✓*         | ✓*                                   | ✓*         |
| Venous Thromboembolism Prophylaxis*****                                                                                             | 0371e      | ✓*         | ✓*         | Proposed for Removal                 |            |
| Intensive Care Unit Venous Thromboembolism Prophylaxis*****                                                                         | 0372e      | ✓*         | ✓*         | Proposed for Removal                 |            |
| Safe Use of Opioids—Concurrent Prescribing                                                                                          | 3316e      | ✓          | ✓          | ✓                                    | ✓          |
| Hospital Harm—Opioid-Related Adverse Events                                                                                         | 3501e      | ✓*         | ✓          | ✓                                    | ✓          |
| Hospital Harm—Severe Hypoglycemia                                                                                                   | 3503e      | ✓          | ✓          | ✓                                    | ✓          |
| Hospital Harm—Severe Hyperglycemia                                                                                                  | 3533e      | ✓          | ✓          | ✓                                    | ✓          |
| Hospital Harm—Pressure Injury                                                                                                       | 3498e      | ✓*         | ✓*         | ✓                                    | ✓          |
| Hospital Harm—Acute Kidney Injury                                                                                                   | 3713e      | ✓*         | ✓*         | ✓                                    | ✓          |
| Hospital Harm—Falls with Injury*****                                                                                                | 4120e      | ✓*         | ✓*         | Proposed for Mandatory Reporting     | ✓          |
| Hospital Harm—Postoperative Respiratory Failure*****                                                                                | 4130e      | ✓*         | ✓*         | Proposed for Mandatory Reporting     | ✓          |
| Hospital Harm—Postoperative Venous Thromboembolism*****                                                                             | 5325e      |            |            | Proposed for Self-selected Reporting | ✓*         |
| Cesarean Birth                                                                                                                      | 0471e      | ✓          | ✓          | ✓                                    | ✓          |
| Severe Obstetric Complications                                                                                                      | 3687e      | ✓          | ✓          | ✓                                    | ✓          |
| Malnutrition Care Score*****                                                                                                        | 3592e      | ✓*         | ✓*         | Proposed for Mandatory Reporting     | ✓          |
| Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient) | 3663e      | ✓*         | ✓*         | ✓*                                   | ✓*         |
| Advance Care Planning*****                                                                                                          | N/A        |            |            | Proposed for Self-Selected Reporting | ✓*         |

✓ Measure is mandatory for the specified payment determination year.

\* Measure is a self-selected eCQM for the specified payment determination year. Hospitals are required to self-select three eCQMs, in addition to all mandatory eCQMs, to submit for the specified payment determination year.

\*\* Proposed for adoption in this proposed rule for the FY 2028 payment determination through the FY 2031 payment determination.

\*\*\* In this proposed rule, we propose modifications to the AMI EDAC, HF EDAC, and PN EDAC measures beginning with the FY 2028 payment determination. We refer readers to section IX.C.5. of the preamble of this proposed rule for more detailed discussion.

\*\*\*\* Proposed for adoption in this proposed rule beginning with FY 2029 payment determination.

\*\*\*\*\* Proposed for removal in this proposed rule beginning with the FY 2030 payment determination.

\*\*\*\*\* Proposed modification in this proposed rule from self-selected to mandatory reporting beginning with the FY 2030 payment determination.

\*\*\*\*\* Proposed for adoption in this proposed rule beginning with the FY 2030 payment determination. We refer readers to section IX.C.8.c. for our proposal to modify reporting and submission requirements for eCQMs; under this proposal the Hospital Harm—Postoperative VTE eCQM would become mandatory after two years of self-selected beginning with the FY 2032 payment determination.

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## 7. Future Considerations

We seek to develop a comprehensive set of quality measures to be widely available for informed decision-making and quality and cost improvements in the hospital inpatient setting. We have identified potential future measures that are focused on topics that are of importance to interested parties, but that are not currently included in the Hospital Inpatient Quality Reporting Program's measure set. We refer readers to section IX.B.3. for our request for comment on "Measuring Emergency Care Access and Timeliness in Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs—Request for Information" and section IX.B.4. for our request for comment on "Potential Future Use of the Adult Community-Onset Sepsis Standardized Mortality Ratio Measure in the Hospital Inpatient Quality Reporting Program—Request for Information".

We are also soliciting comments on our anticipated approach to potential scoring methodologies for the next phase of our Birthing Friendly Hospital designation. We will consider feedback we receive as we determine how best to further develop and refine the Hospital Inpatient Quality Reporting Program's measure set and to advance other quality improvement efforts that address important patient safety and health care quality topics.

#### a. Birthing-Friendly Hospital Designation Modification To Expand Designation Criteria—Request for Information

In this request for information (RFI), we seek public input on potential modifications to the Birthing-Friendly Hospital Designation which was adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49284 through 49290). In the FY 2023 IPPS/LTCH PPS final rule, we noted our intent to expand the Birthing-Friendly Hospital Designation with a more robust set of metrics in future years, and we intended for those additional metrics to potentially be derived from maternal care quality measures from the Hospital Inpatient Quality Reporting Program. This RFI aims to gather broad public input on: (1) the inclusion of the Cesarean Birth eCQM and the Severe Obstetric Complications eCQM in the criteria for awarding the Birthing-Friendly Hospital Designation; and (2) a modified scoring methodology developed for the expanded designation.

#### (1) Background

The Birthing-Friendly Hospital Designation (hereinafter referred to as "the Designation"), was created to identify hospitals that demonstrate the delivery of high-quality maternal care and a commitment to improving maternal health outcomes (87 FR 49284 through 49290). Despite the highest rate of spending on maternity care, maternal morbidity and mortality rates in the United States are high compared to other high-income countries. Every year in the United States, approximately 700 women die of complications related to pregnancy and childbirth, and over 25,000 women experience severe complications of pregnancy (severe maternal morbidity).<sup>362 363</sup> Approximately one-third of all pregnancy-related deaths occur at the time of delivery and immediately postpartum, with nearly 20 percent occurring between one and six days postpartum.<sup>364</sup> Yet, three out of five pregnancy-related deaths are considered preventable.<sup>365</sup>

We believe the Designation is an important way to advance maternal care quality for patients and families and represents our sustained commitment to improving health outcomes. Interested parties expressed support for the Designation as a meaningful step to promote transparency and improve maternal health outcomes. When we proposed the Designation in the FY 2023 IPPS/LTCH PPS proposed rule, many commenters recommended using additional data to determine which hospitals would receive the Designation, including data from the Cesarean Birth and Severe Obstetric Complications eCQMs, rather than just the Maternal Morbidity Structural measure data (87 FR 49284 through 49290).

The Designation was created to be a consumer-friendly, publicly reported display signaling a hospital's

commitment to improving maternal health. Hospitals that are awarded the Designation receive a Birthing-Friendly icon on the Compare tool on *Medicare.gov*. The Designation was first displayed on the Compare tool in Fall 2023 using CY 2022 data. Geocoded information of Birthing-Friendly hospitals and health systems is available at: <https://data.cms.gov/provider-data/birthing-friendly-hospitals-and-health-systems>.

#### (2) Current Birthing-Friendly Hospital Designation Methodology

Currently, the Designation is comprised of the Maternal Morbidity Structural measure adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365). The Maternal Morbidity Structural measure is an attestation-based measure which includes one attestation, currently specified as a two-part question, that captures whether hospitals are: (1) currently participating in a structured state or national Perinatal Quality Improvement (QI) Collaborative; and (2) implementing patient safety practices or bundles as part of these QI initiatives.<sup>366</sup> In reporting this measure, hospitals answer "yes," "no," or "not applicable (our hospital does not provide inpatient labor/delivery care)".<sup>367</sup> The Designation is given to hospitals that report "yes" for the Maternal Morbidity Structural measure. The current version of the Maternal Morbidity Structural measure specifications is available at: <https://qualitynet.cms.gov/inpatient/iqr/measures#tab2>. We note in section IX.C.8.d.(1). of the preamble of this proposed rule where we are proposing to update the reporting requirements of the Maternal Morbidity Structural measure beginning with the CY 2026 reporting period/FY 2028 payment determination.

#### (3) Potential Modifications to the Birthing-Friendly Hospital Designation

Potential modifications to the Designation would include incorporating hospital performance on

<sup>362</sup> Peterson EE et al. Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017. *MMWR Morbidity and Mortality Weekly Report* 2019;68:423–29.

<sup>363</sup> Maternal and Child Health Bureau. Federally Available Data (FAD) Resource Document. Health Resources and Services Administration. Available at: <https://mchb.tvisdata.hrsa.gov/Admin/FileUpload/DownloadContent?fileName=FadResourceDocument.pdf&isForDownload=False>.

<sup>364</sup> Davis N.L., Smoots A.N., and Goodman D.A. (2019). Pregnancy-Related Deaths: Data from 14 U.S. Maternal Mortality Review Committees, 2008–2017. Available at: [https://archive.cdc.gov/www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/MMR-Data-Brief\\_2019-h.pdf](https://archive.cdc.gov/www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/MMR-Data-Brief_2019-h.pdf).

<sup>365</sup> The Centers for Disease Control and Prevention. Pregnancy-Related Deaths in the United States. September 2021. Available at: <https://www.cdc.gov/hearher/pregnancy-related-deaths/index.html>.

<sup>366</sup> Centers for Medicare & Medicaid Services. Cross-Cutting Initiative: CMS Maternity Care Action Plan. 2022. Available at: <https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf>.

<sup>367</sup> To report on this measure, hospitals will respond to a two-part question: "Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and postpartum care, and has it implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?" Further details on this measure can be found in the FY 2022 IPPS/LTCH PPS final rule at 86 FR 45361 through 45365.



two additional maternal care quality outcome measures: (1) the Cesarean Birth eCQM and (2) the Severe Obstetric Complications eCQM. These two eQCMs aim to reduce the occurrence of cesarean deliveries and maternal complications, thereby improving maternal health outcomes and quality of life. Incorporating guidance from a TEP, we developed a potential new scoring methodology for the Designation that aggregates these two measures into a composite score to meaningfully summarize hospital maternal health performance and to determine hospital performance on the Designation.

(a) Expanding the Birthing-Friendly Hospital Designation To Include the Cesarean Birth and the Severe Obstetric Complications Electronic Clinical Quality Measures

The Cesarean Birth eCQM is an outcome measure that assesses the proportion of cesarean deliveries to nulliparous women (women giving birth for the first time) who delivered at 37 weeks' gestation or later with a live singleton baby (a single baby) in a vertex position (head-down). The hospital-level score is calculated as a proportion, for which a lower proportion is better; however, since cesarean delivery is a warranted emergency intervention in certain situations, scores are not expected, nor desired, to approach zero. For further details on the measure methodology, we refer readers to the methodology report available at: <https://manual.jointcommission.org/releases/TJC2023B/MIF0167.html>. The measure became mandatory for all hospitals participating in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs beginning with the CY 2024 reporting period (87 FR 49298 through 49302; 87 FR 49361 through 49364).

The Severe Obstetric Complications eCQM is a risk-standardized measure that assesses severe maternal morbidity events and mortality during delivery hospitalizations for patients greater than or equal to 8 years and less than 65 years of age delivering stillborn or a live birth at greater than or equal to 20 weeks' gestation. The measure evaluates two outcomes: (1) any severe obstetric complications (as specified), and (2) severe obstetric complications excluding encounters for which blood transfusion was the only numerator event. For both outcomes, the hospital-level score is reported as a rate per 10,000 delivery hospitalizations, for which a lower score is better. For further details on the measure methodology, we refer readers to the methodology report available at: [https://ecqi.healthit.gov/sites/default/files/SevereObstetricComplications%20eCQM\\_Methodology%20Report%20-%20Dec%202022.pdf](https://ecqi.healthit.gov/sites/default/files/SevereObstetricComplications%20eCQM_Methodology%20Report%20-%20Dec%202022.pdf). The measure became mandatory for all hospitals participating in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs beginning with the CY 2024 reporting period (87 FR 49298 through 49302; 87 FR 49361 through 49364).

(b) Potential New Scoring Methodology

Following careful assessment of various scoring approaches, we determined the composite score approach with k-means clustering to be a strong approach for calculating hospital Designation scores. The composite score approach with k-means clustering enables a tiered approach to award the Designation, thus allowing for a range of hospital performance while still recognizing high-performing hospitals. In addition, this approach allows for differential weighting, enabling more outcome related measures to have a stronger influence on the overall performance scores. This approach is similar to that used in the Overall Hospital Quality Star Rating methodology (85 FR 86193 through 86236).<sup>368</sup>

To be eligible for the expanded Designation, hospitals would have to attest positively to the Maternal Morbidity Structural measure and report on both maternal outcome measures (Cesarean Birth and Severe Obstetric Complications eQCMs). Positive attestation to the Maternal Morbidity Structural measure would be required for Designation eligibility and would serve as a prerequisite to obtaining the Designation. Once hospital eligibility is determined, the methodology for aggregating hospital scores for the two maternal outcome measures into a composite and scoring for the Designation would include a series of steps. First, the direction of measure scores is changed so that a higher score indicates better performance for all the measures. Second, measure scores that do not follow a normal distribution are normalized by applying a log transformation, and then the data are standardized using Z-scores<sup>369</sup> to enable aggregation on a common scale.

Third, measure scores are multiplied by assigned weights. The Cesarean Birth eCQM is assigned a 45 percent weight. The two outcomes for the Severe Obstetric Complications eCQM are assigned weights that sum to 55 percent: 18 percent for any severe obstetric complications, and 37 percent for severe obstetric complications excluding encounters for which blood transfusion was the only numerator event. The higher weighting of the Severe Obstetric Complications eCQM was selected because it prioritizes the occurrence of severe obstetric complications and elevates attention to reducing maternal morbidity. Furthermore, the differential weighting among the two Severe Obstetric Complications eCQM outcomes was selected to prioritize the outcome excluding blood transfusion-only encounters, as these encounters may represent lesser severity than the other specified obstetric complications. Fourth, weighted measure scores are aggregated to generate the composite score for each hospital. Fifth, hospitals are grouped into four peer groups based on the delivery volume for that hospital during the performance period (less than or equal to 500 deliveries, 501 to 1000 deliveries, 1001 to 2000 deliveries, and greater than 2000 deliveries). Peer grouping by hospital delivery volume supports comparison of hospitals with obstetric units of similar scale. Sixth, a statistical clustering algorithm (k-means clustering) is applied within each peer group to assign hospitals with similar composite scores to one of three clusters representing levels of maternal care quality. For details of this potential future modified measure methodology for scoring an expanded Designation, we refer readers to the draft methodology report, available at: <https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures>.

<sup>368</sup> Available at: <https://data.cms.gov/provider-data/topics/hospitals/overall-hospital-quality-star-rating/>.

<sup>369</sup> Z-score standardization is a commonly used approach that translates hospital results into a common scale, indicating how each hospital's performance compares with the overall average. This approach helps reduce the impact of extreme values and differences in scoring methods, while supporting fair and consistent comparisons across hospitals.

(c) Awarding the Birthing-Friendly Hospital Designation

For the current Birthing-Friendly Hospital Designation, hospitals receive the Designation for positively attesting to the Maternal Morbidity Structural measure. The potential new scoring methodology described previously would introduce a tiered approach to awarding the Designation by performance relative to other hospitals on multiple maternal quality measures, and shifts away from a binary approach that only identifies hospitals as "Birthing-Friendly" or, by default, as "non-Birthing-Friendly." The potential new approach considers the range in maternal care performance among labor and delivery hospitals and allows for recognition of the highest-performing

hospitals. As positive attestation to the Maternal Morbidity Structural measure would serve as a prerequisite to receiving the Designation, hospitals currently awarded the Designation could maintain “Birthing-Friendly” status.

Within delivery volume peer groups, hospitals would be assigned to one of three clusters based on composite score, where cluster three consists of hospitals with the highest level of performance (highest composite scores) and cluster one consists of hospitals with the lowest level of performance (lowest composite scores). Each cluster would be represented by a corresponding number of Birthing-Friendly icons (similar to a star rating) such that hospitals in cluster one would be identified with one Birthing-Friendly icon (identifying the lowest performing hospitals), hospitals in cluster two would be identified with two Birthing-Friendly icons, and hospitals in cluster three would be identified with three Birthing-Friendly icons (identifying the top performing hospitals).

The use of peer grouping by hospital delivery volume to award the Designation allows for comparison of

like hospitals, grouping facilities with obstetric units of similar scale. Other variables for peer grouping the Designation were considered, with particular attention to using Maternal Levels of Care in anticipation that hospitals providing different levels of care vary in patient case mix. The Maternal Levels of Care, a classification system developed by the American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine to support risk-appropriate maternal care delivery, is used to classify hospitals providing labor and delivery services from “Basic Care” (Level I) for women with low to moderate-risk pregnancies to “Regional Perinatal Health Care Centers” (Level IV) for women inclusive of those at low-risk to the highest-risk pregnancies.<sup>370</sup> However, there is currently no reliable and comprehensive source of publicly reported data on Maternal Levels of Care for all hospitals providing labor and delivery services. In this RFI, we seek further input on peer grouping considerations.

In preliminary testing of the modified Designation scoring methodology, 2,548 hospitals that reported at least one of

the maternal measures for CY 2024 were identified (excluding hospitals that responded “not applicable (our hospital does not provide inpatient labor/delivery care)” to the Maternal Morbidity Structural measure). Among these, 1,976 hospitals were determined to have reported on all three measures and had 25 or more delivery hospitalizations during the measurement period, to align with the public reporting threshold for the maternal outcome measures. Of these hospitals, 1,920 (97.1 percent) hospitals attested positively to the Maternal Morbidity Structural measure and were included in testing of the modified Designation scoring methodology. Preliminary results indicate variation in mean composite scores for the Designation clusters across delivery volume categories (peer groups), most distinctly for the top delivery volume category (hospitals with greater than 2000 deliveries) that had a lower mean composite score within each cluster as compared to the mean composite scores of those clusters in lower delivery volume categories (see Table IX.C.6.).

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**TABLE IX.C.6.: MEAN BIRTHING-FRIENDLY HOSPITAL DESIGNATION COMPOSITE SCORE PER CLUSTER FOR EACH DELIVERY VOLUME CATEGORY (PEER GROUP), CY 2024 TESTING DATA (N = 1920 HOSPITALS)**

| Delivery Volume Categories | Cluster 1<br>(Lowest Performing) | Cluster 2 | Cluster 3<br>(Highest Performing) |
|----------------------------|----------------------------------|-----------|-----------------------------------|
| ≤ 500                      | -0.75                            | 0.09      | 0.81                              |
| 501 – 1,000                | -0.66                            | 0.13      | 0.85                              |
| 1,001 – 2,000              | -0.78                            | 0.03      | 0.71                              |
| > 2,000                    | -0.94                            | -0.21     | 0.59                              |

Preliminary testing results for awarding Birthing-Friendly Hospital Designation icons indicate similar

distributions across delivery volume categories (peer groups) for hospitals to receive one, two, and three Birthing-

Friendly icons representing lowest to highest Birthing-Friendly hospital performance (see Table IX.C.7.).

**TABLE IX.C.7.: DISTRIBUTION OF BIRTHING-FRIENDLY HOSPITAL DESIGNATION FOR EACH DELIVERY VOLUME CATEGORY (PEER GROUP), CY 2024 TESTING DATA (N = 1920 HOSPITALS)**

| Peer Groups<br>(Delivery Volume Categories) | Cluster 1<br>(Lowest Performing) | Cluster 2 | Cluster 3<br>(Highest Performing) |
|---------------------------------------------|----------------------------------|-----------|-----------------------------------|
| ≤ 500                                       | 24%                              | 44%       | 32%                               |
| 501 – 1,000                                 | 27%                              | 43%       | 30%                               |
| 1,001 – 2,000                               | 26%                              | 45%       | 29%                               |
| > 2,000                                     | 28%                              | 46%       | 26%                               |

<sup>370</sup> Available at: <https://www.acog.org/programs/lomc>.

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The measure developer received feedback during winter 2025 from a TEP, including patients, patient advocates, technical experts, and clinicians, supporting the expansion of criteria for the Designation and the potential new scoring methodology.<sup>371</sup>

## (4) Solicitation of Public Comments

We seek feedback on potential modifications to the current Birthing-Friendly Hospital Designation. We are requesting input from interested parties on the following potential modifications: (1) expanding the Designation to include two maternal care quality outcome measures: Cesarean Birth eCQM and Severe Obstetric Complications eCQM; (2) the outlined scoring methodology noted previously including use of peer grouping; and (3) the accompanying tiered approach to awarding Birthing-Friendly Hospital Designation icons. Specifically, we are requesting feedback on the following topics:

- Do you have feedback on the potential new scoring methodology outlined in this RFI for the Designation?

- With respect to the potential new scoring methodology, do you have any special considerations for small, rural, or safety net hospitals?

- Differential measure score weighting:

- ++ Do you have feedback on the higher weighting of the Severe Obstetric Complications eCQM (combined scores) at 55 percent compared to weighting of the Cesarean Birth eCQM at 45 percent?

- ++ Do you have feedback on the differential weighting of the two Severe Obstetric Complications eCQM outcomes (any severe obstetric complication equals 18 percent, severe obstetric complications excluding encounters for which blood transfusion was the only numerator event equals 37 percent)?

- Do you have feedback on a tiered approach to awarding the Designation for identifying levels of quality/performance?

- Approaches for peer grouping:

- ++ Do you have feedback on using delivery volume as a peer grouping variable?

- ++ Would the category “less than or equal to 500 deliveries” represent an appropriate peer grouping for hospitals with low birth volumes, such as those in rural areas?

- ++ Should there be a minimum number of births required in the peer grouping, such as “25–500 deliveries” instead of “less than or equal to 500 deliveries”?

- ++ Are there any other variables that would be appropriate for peer grouping? And if so, please provide information on data sources.

- Public reporting of the Designation results:

- ++ Do you have feedback on the presentation of the Designation on the Compare tool? Specifically, do you agree with using one to three Birthing-Friendly icons to represent summarized hospital performance?

- ++ Is the Designation easily interpreted by patients and consumers? Do you have suggestions on the messaging of the Designation on the Compare tool on Medicare.gov?

With these questions, we are seeking public input on potential modifications to the Birthing-Friendly Hospital Designation described previously, for consideration in future rulemaking.

## 8. Updates to the Form, Manner, and Timing of Quality Data Submission

We are proposing changes to our reporting and submission requirements for eQMs and structural measures, as later discussed in this proposed rule.

We are not proposing any changes to the following requirements: procedural requirements; data submission requirements for chart-abstracted measures; data submission and reporting requirements for hybrid measures; sampling and case thresholds for chart-abstracted measures; HCAHPS Survey administration and submission requirements; data submission and reporting requirements for CDC National Healthcare Safety Network measures; and data submission and reporting requirements for Patient-Reported Outcome-Based Performance Measures. Accordingly, these requirements will not be repeated in the Form, Manner, and Timing of Quality Data Submission section. We refer readers to the QualityNet website at: <https://qualitynet.cms.gov/inpatient/iqr> (or other successor CMS designated websites) for more details on the Hospital Inpatient Quality Reporting Program data submission and procedural requirements.

## a. Background

Section 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections

1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner and at a time specified by the Secretary. To successfully participate in the Hospital Inpatient Quality Reporting Program, hospitals must meet specific procedural, data collection, submission, and validation requirements.

## b. Maintenance of Technical Specifications for Quality Measures

Section 412.140(c)(1) of title 42 of the CFR generally requires that a subsection (d) hospital participating in the Hospital Inpatient Quality Reporting Program must submit to CMS data on measures selected under section 1886(b)(3)(B)(viii) of the Act in a form and manner, and at a time, specified by CMS. The data submission requirements, specifications manual, measure methodology reports, and submission deadlines are posted on the QualityNet website at: <https://qualitynet.cms.gov> (or other successor CMS designated websites).

The CMS Annual Update for the Hospital Quality Reporting (HQR) Programs (Annual Update) contains the technical specifications for eQMs. The updated measure specifications applicable to a reporting period are contained in the Annual Update issued in the year prior to the reporting period. For example, for the CY 2026 reporting period/FY 2028 payment determination, hospitals are collecting and will submit eCQM data using the May 2025 Annual Update and any applicable addenda. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: <https://ecqi.healthit.gov/>.

Hospitals must register and submit quality data as described at 42 CFR 412.140(a).

## c. Data Submission and Reporting Requirements for Electronic Clinical Quality Measures

## (1) Background

Beginning with the CY 2016 reporting period, we began requiring hospitals to report on eQMs with the goal of progressively increasing the number of eQMs a hospital is required to report while also being responsive to concerns about timing, readiness, and burden associated with the increased number of measures (80 FR 49693 through 49698 and 81 FR 57150 through 57157). Over time we have gradually increased the number of eQMs that we require

<sup>371</sup> Yale CORE. (March 2026). Summary of Technical Expert Panel (TEP): Development of Birthing Friendly Hospital Designation (BFHD). Available at: <https://mmshub.cms.gov/sites/default/files/Del4-3BFHDSummaryTEPEvaluation-March2026.pdf>.

hospitals to report over the course of several years to allow hospitals and their vendors time to gain experience with reporting eCQMs, while providing flexibility by retaining an element of choice in allowing a hospital to self-select some eCQMs (84 FR 42503

through 42505, 85 FR 58932 through 58939, 86 FR 45417 through 45418, 87 FR 49298 through 49302, and 89 FR 69568 through 69573). In the FY 2025 IPPS/LTCH PPS final rule, we finalized a further increase in the number of mandatory eCQMs focused on

improving patient safety (89 FR 69568 through 69573). Table IX.C.8. summarizes our current eCQM reporting and submission policies:

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**TABLE IX.C.8. PREVIOUSLY FINALIZED ECQM REPORTING AND SUBMISSION REQUIREMENTS FOR THE CY 2026 REPORTING PERIOD/FY 2028 PAYMENT DETERMINATION AND SUBSEQUENT YEARS**

| Reporting Period/<br>Payment<br>Determination           | Total Number<br>of eCQMs<br>Reported | eCQMs Selected by CMS to be Reported                                                                                                                                                                                                                                                                                                                                                                       | eCQMs for Self-selection (must report 3)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------------------------------------------------|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CY 2026/<br>FY 2028                                     | Eight                                | <ul style="list-style-type: none"> <li>• Safe Use of Opioids—Concurrent Prescribing</li> <li>• Cesarean Birth</li> <li>• Severe Obstetric Complications</li> <li>• Hospital Harm—Severe Hyperglycemia</li> <li>• Hospital Harm—Severe Hypoglycemia</li> </ul>                                                                                                                                              | <ul style="list-style-type: none"> <li>• Discharged on Antithrombotic Therapy</li> <li>• Anticoagulation Therapy for Atrial Fibrillation/Flutter</li> <li>• Antithrombotic Therapy by the End of Hospital Day Two</li> <li>• Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults</li> <li>• Venous Thromboembolism Prophylaxis</li> <li>• Intensive Care Unit Venous Thromboembolism Prophylaxis</li> <li>• Malnutrition Care Score</li> <li>• Hospital Harm—Opioid-Related Adverse Events</li> <li>• Hospital Harm—Pressure Injury</li> <li>• Hospital Harm—Acute Kidney Injury</li> <li>• Hospital Harm—Falls with Injury</li> <li>• Hospital Harm—Postoperative Respiratory Failure</li> </ul> |
| CY 2027/<br>FY 2029                                     | Nine                                 | <ul style="list-style-type: none"> <li>• Safe Use of Opioids—Concurrent Prescribing</li> <li>• Cesarean Birth</li> <li>• Severe Obstetric Complications</li> <li>• Hospital Harm—Severe Hyperglycemia</li> <li>• Hospital Harm—Severe Hypoglycemia</li> <li>• Hospital Harm—Opioid-Related Adverse Events</li> </ul>                                                                                       | <ul style="list-style-type: none"> <li>• Discharged on Antithrombotic Therapy</li> <li>• Anticoagulation Therapy for Atrial Fibrillation/Flutter</li> <li>• Antithrombotic Therapy by the End of Hospital Day Two</li> <li>• Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults</li> <li>• Venous Thromboembolism Prophylaxis</li> <li>• Intensive Care Unit Venous Thromboembolism Prophylaxis</li> <li>• Malnutrition Care Score</li> <li>• Hospital Harm—Pressure Injury</li> <li>• Hospital Harm—Acute Kidney Injury</li> <li>• Hospital Harm—Falls with Injury</li> <li>• Hospital Harm—Postoperative Respiratory Failure</li> </ul>                                                        |
| CY 2028/<br>FY 2030<br>(and for<br>subsequent<br>years) | Eleven                               | <ul style="list-style-type: none"> <li>• Safe Use of Opioids—Concurrent Prescribing</li> <li>• Cesarean Birth</li> <li>• Severe Obstetric Complications</li> <li>• Hospital Harm—Severe Hyperglycemia</li> <li>• Hospital Harm—Severe Hypoglycemia</li> <li>• Hospital Harm—Opioid-Related Adverse Events</li> <li>• Hospital Harm—Pressure Injury</li> <li>• Hospital Harm—Acute Kidney Injury</li> </ul> | <ul style="list-style-type: none"> <li>• Discharged on Antithrombotic Therapy</li> <li>• Anticoagulation Therapy for Atrial Fibrillation/Flutter</li> <li>• Antithrombotic Therapy by the End of Hospital Day Two</li> <li>• Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults</li> <li>• Venous Thromboembolism Prophylaxis</li> <li>• Intensive Care Unit Venous Thromboembolism Prophylaxis</li> <li>• Malnutrition Care Score</li> <li>• Hospital Harm—Falls with Injury</li> <li>• Hospital Harm—Postoperative Respiratory Failure</li> </ul>                                                                                                                                              |

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We refer readers to the QualityNet website for additional information on current and previous reporting and submission requirements for eCQMs at: <https://qualitynet.cms.gov/inpatient/measures/ecqm>.

(2) Proposal for Mandatory Reporting of the Malnutrition Care Score Electronic Clinical Quality Measure

The Malnutrition Care Score eCQM was initially adopted in the FY 2023 IPPS/LTCH PPS final rule into the

Hospital Inpatient Quality Reporting Program measure set from which a hospital could self-select beginning with the CY 2024 reporting period/FY 2026 payment determination (87 FR 49239 through 49246). In the FY 2025 IPPS/

LTCH PPS final rule, we modified the measure to include patients 18 years old and older in the measure cohort, beginning with the CY 2026 reporting period/FY 2028 payment determination (89 FR 69557 through 69560). In the FY 2026 IPPS/LTCH PPS final rule, we summarized input we received through the public comment process in response to our RFI on measure concepts of well-being and nutrition for future years in the Hospital Inpatient Quality Reporting Program and other quality measure programs; many commenters supported the utilization of the Malnutrition Care Score eCQM, noting it plays a critical role in identifying and addressing nutritional concerns in the hospital inpatient setting, and some commenters specifically supported making the Malnutrition Care Score eCQM mandatory (90 FR 36996 through 36997).

In consideration of these public comments and in alignment with the administration's priority focus on well-being and nutrition, we are proposing mandatory reporting of the Malnutrition Care Score eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination. This proposal also aligns with our ongoing strategy to transition to a fully digital quality measurement landscape that promotes interoperability, reduces reporting burden, and increases the value of reporting quality measure data (90 FR 36990 through 36996). If this proposal is finalized, hospitals would have an opportunity to continue to self-select this eCQM for the CY 2026 and CY 2027 reporting periods before mandatory reporting for all hospitals would begin

with the CY 2028 reporting period/FY 2030 payment determination.

### (3) Proposal for Mandatory Reporting of the Hospital Harm Electronic Clinical Quality Measures

We previously implemented a stepwise approach to increase the number of required eCQMs in response to public comments noting the burden and resources necessary to implement new eCQMs (89 FR 69568 through 69573). This approach balances the need to prioritize more comprehensive reporting on important safety and preventable harm metrics with the need to provide hospitals and health IT vendors time to implement new eCQMs.

Currently, in the Hospital Inpatient Quality Reporting Program, we have adopted seven eCQMs aimed at addressing different types of and various aspects of preventable hospital harms: Hospital Harm—Severe Hyperglycemia; Hospital Harm—Severe Hypoglycemia; Hospital Harm—Opioid-Related Adverse Events; Hospital Harm—Pressure Injury; Hospital Harm—Acute Kidney Injury; Hospital Harm—Falls with Injury; and Hospital Harm—Postoperative Respiratory Failure. On average, less than 10 percent of hospitals self-select to report on a given eCQM in the first year it is available, and we assume a hospital tends to self-select a given eCQM because it will perform better on that eCQM compared to other eCQMs available to self-select. Because hospital harms remain a significant source of morbidity, mortality, and cost, and because of the importance of publicly reporting these metrics to promote

patient safety, we propose to build on the stepwise approach for increasing the number of required eCQMs by modifying the eCQM reporting and submission requirements for Hospital Harm eCQMs. Specifically, we propose that beginning with the CY 2028 reporting period/FY 2030 payment determination, Hospital Harm eCQMs that have not yet been finalized for mandatory reporting would become mandatory in the third year of reporting.

Under this proposal, the Hospital Harm—Falls with Injury eCQM and the Hospital Harm—Postoperative Respiratory Failure eCQM would begin mandatory reporting in CY 2028 reporting period/FY 2030 payment determination. We also propose that the Hospital Harm—Postoperative VTE eCQM, proposed for adoption in section IX.C.3.b. of this proposed rule, would become mandatory to report beginning with the CY 2030 reporting period/FY 2032 payment determination, after being available for 2 years of self-selected reporting. Furthermore, we propose that in subsequent years, newly adopted Hospital Harm eCQMs would become mandatory eCQMs for reporting after 2 years of self-selected reporting in the Hospital Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program. We are not proposing changes to our previously finalized policy that progressively increases the number of mandatory eCQMs a hospital must report for the CY 2026 reporting period/FY 2028 payment determination or the CY 2027 reporting period/FY 2029 payment determination (89 FR 69568 through 69573).

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**TABLE IX.C.9. PROPOSED HOSPITAL HARM ECQM REPORTING AND  
SUBMISSION REQUIREMENTS FOR THE CY 2028 REPORTING PERIOD/FY 2030  
PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS**

| <b>Reporting Period/ Payment Determination</b> | <b>Hospital Harm eQMs Required to be Reported</b>                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CY 2028/FY 2030                                | <ul style="list-style-type: none"> <li>● Hospital Harm—Severe Hyperglycemia</li> <li>● Hospital Harm—Severe Hypoglycemia</li> <li>● Hospital Harm—Opioid-Related Adverse Events</li> <li>● Hospital Harm—Pressure Injury</li> <li>● Hospital Harm—Acute Kidney Injury</li> <li>● Hospital Harm—Falls with Injury*</li> <li>● Hospital Harm—Postoperative Respiratory Failure*</li> </ul>                                                                 |
| CY 2029/FY 2031                                | <ul style="list-style-type: none"> <li>● Hospital Harm—Severe Hyperglycemia</li> <li>● Hospital Harm—Severe Hypoglycemia</li> <li>● Hospital Harm—Opioid-Related Adverse Events</li> <li>● Hospital Harm—Pressure Injury</li> <li>● Hospital Harm—Acute Kidney Injury</li> <li>● Hospital Harm—Falls with Injury*</li> <li>● Hospital Harm—Postoperative Respiratory Failure*</li> </ul>                                                                 |
| CY 2030/FY 2032 (and for subsequent years)     | <ul style="list-style-type: none"> <li>● Hospital Harm—Severe Hyperglycemia</li> <li>● Hospital Harm—Severe Hypoglycemia</li> <li>● Hospital Harm—Opioid-Related Adverse Events</li> <li>● Hospital Harm—Pressure Injury</li> <li>● Hospital Harm—Acute Kidney Injury</li> <li>● Hospital Harm—Falls with Injury*</li> <li>● Hospital Harm—Postoperative Respiratory Failure*</li> <li>● Hospital Harm—Postoperative Venous Thromboembolism**</li> </ul> |

\* Proposed modification in this proposed rule from self-selected to mandatory reporting beginning with the FY 2030 payment determination.

\*\* Proposed for adoption in this proposed rule as a self-selected eCQM beginning with the FY 2030 payment determination. Under this proposal the Hospital Harm—Postoperative VTE eCQM would become mandatory after 2 years of self-selected beginning with the FY 2032 payment determination.

This proposal would advance the transition to a fully digital quality measure set, standardize safety data collection, and improve patient safety by having all hospitals report these measures. By the CY 2028 reporting period/FY 2030 payment determination, hospitals will have had 12 years of progressive experience reporting eQMs. We believe hospitals have built a strong foundation of eCQM reporting through this phased ramp-up to accommodate newly adopted Hospital Harm eQMs into the mandatory measure set for the Hospital Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program after 2 years of self-selected reporting. By making the Hospital Harm eQMs mandatory after 2 years of self-

selected reporting, we ensure that we would receive a robust national dataset for measures on these important topics, and these measures could serve as potential replacements for claims-based measures, such as those reported within the Patient Safety and Adverse Events Composite (PSI 90).

(4) Summary of Proposed Changes to the eCQM Reporting and Submission Requirements

We refer readers to section IX.C.6. for the full list of eQMs by payment determination year in the Hospital Inpatient Quality Reporting Program. If a hospital does not have patients that meet the denominator criteria for any of the eQMs included in this proposal, the hospital would submit a zero denominator declaration. The

submission of a zero denominator declaration allows a hospital to meet the reporting requirements for a particular eCQM. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 and 57170) for our previously adopted eCQM file format requirements. A QRDA Category I file with patients meeting the initial patient population of the applicable measures, a zero denominator declaration, or a case threshold exemption all count toward a successful submission for eQMs for the Hospital Inpatient Quality Reporting Program (82 FR 38387). The following Table IX.C.10. summarizes our proposed policies:

**TABLE IX.C.10. PROPOSED ECQM REPORTING AND SUBMISSION REQUIREMENTS FOR THE CY 2028 REPORTING PERIOD/FY 2030 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS**

| Reporting Period/<br>Payment<br>Determination    | Total Number<br>of eQMs<br>Reported | eQMs Selected by CMS to be Reported                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | eQMs for Self-selection (must report 3)                                                                                                                                                                                                                                                                                                                                      |
|--------------------------------------------------|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CY 2028/<br>FY 2030                              | Fourteen                            | <ul style="list-style-type: none"> <li>• Safe Use of Opioids—Concurrent Prescribing</li> <li>• Cesarean Birth</li> <li>• Severe Obstetric Complications</li> <li>• Malnutrition Care Score*</li> <li>• Hospital Harm—Severe Hyperglycemia</li> <li>• Hospital Harm—Severe Hypoglycemia</li> <li>• Hospital Harm—Opioid-Related Adverse Events</li> <li>• Hospital Harm—Pressure Injury</li> <li>• Hospital Harm—Acute Kidney Injury</li> <li>• Hospital Harm—Falls with Injury*</li> <li>• Hospital Harm—Postoperative Respiratory Failure*</li> </ul>                                                                  | <ul style="list-style-type: none"> <li>• Anticoagulation Therapy for Atrial Fibrillation/Flutter</li> <li>• Antithrombotic Therapy by the End of Hospital Day Two</li> <li>• Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults</li> <li>• Advance Care Planning**</li> <li>• Hospital Harm—Postoperative Venous Thromboembolism***</li> </ul> |
| CY 2029/<br>FY 2031                              | Fourteen                            | <ul style="list-style-type: none"> <li>• Safe Use of Opioids—Concurrent Prescribing</li> <li>• Cesarean Birth</li> <li>• Severe Obstetric Complications</li> <li>• Malnutrition Care Score*</li> <li>• Hospital Harm—Severe Hyperglycemia</li> <li>• Hospital Harm—Severe Hypoglycemia</li> <li>• Hospital Harm—Opioid-Related Adverse Events</li> <li>• Hospital Harm—Pressure Injury</li> <li>• Hospital Harm—Acute Kidney Injury</li> <li>• Hospital Harm—Falls with Injury*</li> <li>• Hospital Harm—Postoperative Respiratory Failure*</li> </ul>                                                                  | <ul style="list-style-type: none"> <li>• Anticoagulation Therapy for Atrial Fibrillation/Flutter</li> <li>• Antithrombotic Therapy by the End of Hospital Day Two</li> <li>• Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults</li> <li>• Advance Care Planning**</li> <li>• Hospital Harm—Postoperative Venous Thromboembolism***</li> </ul> |
| CY 2030/<br>FY 2032<br>(and subsequent<br>years) | Fifteen                             | <ul style="list-style-type: none"> <li>• Safe Use of Opioids—Concurrent Prescribing</li> <li>• Cesarean Birth</li> <li>• Severe Obstetric Complications</li> <li>• Malnutrition Care Score*</li> <li>• Hospital Harm—Severe Hyperglycemia</li> <li>• Hospital Harm—Severe Hypoglycemia</li> <li>• Hospital Harm—Opioid-Related Adverse Events</li> <li>• Hospital Harm—Pressure Injury</li> <li>• Hospital Harm—Acute Kidney Injury</li> <li>• Hospital Harm—Falls with Injury*</li> <li>• Hospital Harm—Postoperative Respiratory Failure*</li> <li>• Hospital Harm—Postoperative Venous Thromboembolism***</li> </ul> | <ul style="list-style-type: none"> <li>• Anticoagulation Therapy for Atrial Fibrillation/Flutter</li> <li>• Antithrombotic Therapy by the End of Hospital Day Two</li> <li>• Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults</li> <li>• Advance Care Planning**</li> </ul>                                                                  |

\* Proposed modification in this proposed rule from self-selected to mandatory reporting beginning with the FY 2030 payment determination.

\*\* Proposed for adoption in this proposed rule as a self-selected eCQM beginning with the FY 2030 payment determination.

\*\*\* Proposed for adoption in this proposed rule as a self-selected eCQM beginning with the FY 2030 payment determination. If this proposal and our proposal to modify the eCQM reporting requirements for Hospital Harm eQMs are finalized, the Hospital Harm—Postoperative VTE eCQM would become mandatory after two years of self-selected beginning with the FY 2032 payment determination.

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We invite public comment on our proposals to require hospitals to report on the Malnutrition Care Score eCQM and on all current and future Hospital Harm eQMs after 2 years of self-selected reporting beginning with CY 2028 reporting period/FY 2030 payment determination. We refer readers to

section IX.F.9. of this proposed rule, in which we propose the same reporting and submission requirements for eQMs under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.

**d. Data Submission and Reporting Requirements for Structural Measures**

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 and 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 and 53539) for details on the data submission requirements for structural measures.

We propose an update to the reporting and submission requirements for the Maternal Morbidity Structural measure beginning with the FY 2028 payment determination.

(1) Proposed Update to Maternal Morbidity Structural Measure Reporting

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365), we adopted the Maternal Morbidity Structural measure beginning with the FY 2023 payment determination. In this attestation-based measure, hospitals answer the following two-part question: *Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and postpartum care, and has it implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?*<sup>372</sup> The answer choices are “yes”, “no”, or “not applicable” (for hospitals that do not provide inpatient labor/delivery care).

To improve the completeness and usefulness of the data collected, we propose updating the reporting requirements. Specifically, if a hospital answers “yes” to the measure as currently specified, the hospital would also need to report the name of the perinatal quality improvement collaborative program. In the HQR System, if a hospital selects “yes” in response to the measure, the hospital would also be prompted to report a response to the following: “Which Statewide and/or National Perinatal Quality Improvement Collaborative Program does the hospital participate in?” This change is intended to enhance our understanding of current practices and support targeted quality improvement efforts. This update to the reporting requirements of the measure would not impact measure performance, as the criteria for attesting “yes” to the measure remain the same. However, we would not consider a hospital which attested “yes” to the measure but did not provide the name of the perinatal quality improvement collaborative program in which they participate to have successfully reported all requirements for this measure. Therefore, such a hospital would be subject to a payment penalty. To report

on this measure, hospitals would continue using the CMS-approved web-based collection tool available within the HQR System once annually, as they currently do to report for this and other Hospital Inpatient Quality Reporting Program structural measures (87 FR 49304 through 49305).

We invite public comment on our proposed update to the reporting requirements for the Maternal Morbidity Structural measure beginning with the CY 2026 reporting period/FY 2028 payment determination.

*D. PPS-Exempt Cancer Hospital Quality Reporting Program*

1. Background and History of the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program

The PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program, authorized by section 1866(k) of the Act, applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as “PPS-Exempt Cancer Hospitals” or “PCHs”). We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53555 through 53567) for a general overview of the PCH Quality Reporting Program. We also refer readers to 42 CFR 412.24 for codified PCH Quality Reporting Program requirements.

2. Proposed New Measures for the PCH Quality Reporting Program Measure Set

We propose to adopt two new measures into the PCH Quality Reporting Program: (1) Advance Care Planning electronic clinical quality measure (eCQM) for a full year of reporting beginning with the CY 2028 reporting period/FY 2030 program year; and (2) Malnutrition Care Score eCQM for a full year of reporting beginning with the CY 2028 reporting period/FY 2030 program year. We provide more details on the proposed adoption of the Malnutrition Care Score eCQM in section IX.D.2.a. of the preamble of this proposed rule, while details on the proposed adoption of the Advance Care Planning eCQM measure appear in section IX.B.1. of the preamble of this proposed rule.

a. Proposed Adoption of the Malnutrition Care Score Electronic Clinical Quality Measure

(1) Background

Malnutrition is a common and high-risk condition characterized by unbalanced nutrition, encompassing both undernutrition and overnutrition.<sup>373</sup> Undernutrition occurs

when an individual has insufficient calories, protein, or other nutrients from inadequate intake, impaired absorption, increased metabolic demands, or increased nutrient losses. Overnutrition includes a surplus of calories, which increases risk for obesity, type 2 diabetes, heart attacks, strokes, and other chronic conditions.<sup>374</sup> Malnutrition can be more prevalent among hospitalized patients with cancer and is associated with increased health care costs and adverse clinical outcomes, including increased length of hospital stays, complications and readmission rates, and all-cause mortality risk.<sup>375</sup> Up to an estimated 80 percent of cancer patients experience malnutrition, with prevalence varying based on cancer stage, type, treatment route, and the patient’s age.<sup>376</sup> Adult cancer patients at risk of malnutrition have a 70 percent higher risk for all-cause mortality and a 49 percent higher risk for chemotherapy-related complications compared to patients with no malnutrition risk.<sup>377</sup> Furthermore, the side effects of cancer treatments, such as chemotherapy and radiation therapy, can impair nutritional intake due to nausea, vomiting, early satiety, and taste changes.<sup>378</sup> These effects underscore the need for nutrition screening throughout cancer treatment to maintain patient health, minimize nutrition-related side effects, and ultimately ensure the ability to keep a patient on an effective treatment schedule.

[www.eatright.org/health/health-conditions/malnutrition-and-deficiencies/what-is-malnutrition](http://www.eatright.org/health/health-conditions/malnutrition-and-deficiencies/what-is-malnutrition).

<sup>374</sup> Academy of Nutrition and Dietetics. (2022).

How an RDN Can Help with Malnutrition.

Available at: <https://www.eatright.org/health/health-conditions/malnutrition-and-deficiencies/how-an-rdn-can-help-with-malnutrition>.

<sup>375</sup> Corriveau J, Alavifard D, Gillis C. (2022).

Demystifying Malnutrition to Improve Nutrition Screening and Assessment in Oncology. *Seminars in Oncology Nursing*, 38(5). <https://doi.org/10.1016/j.soncn.2022.151336>.

<sup>376</sup> Hoobler R, Herrera M, Woodruff K, Sanchez A, Coletta AM, Chaix A, Elizondo J, Playdon MC. (2025). Malnutrition Risk Is Associated With All-Cause Mortality and Chemotherapy Complications Among Adults Diagnosed With Diverse Cancer Types: A Retrospective Cohort Study. *Journal of the Academy of Nutrition and Dietetics*, 125(9), 1242–1255. <https://doi.org/10.1016/j.jand.2025.04.014>.

<sup>377</sup> Hoobler R, Herrera M, Woodruff K, Sanchez A, Coletta AM, Chaix A, Elizondo J, Playdon MC. (2025). Malnutrition Risk Is Associated With All-Cause Mortality and Chemotherapy Complications Among Adults Diagnosed With Diverse Cancer Types: A Retrospective Cohort Study. *Journal of the Academy of Nutrition and Dietetics*, 125(9), 1242–1255. <https://doi.org/10.1016/j.jand.2025.04.014>.

<sup>378</sup> PDQ® Supportive and Palliative Care Editorial Board. PDQ Nutrition in Cancer Care. Bethesda, MD: National Cancer Institute. Updated 09/20/2024. Available at: <https://www.cancer.gov/about-cancer/treatment/side-effects/appetite-loss/nutrition-hp-pdq>.

<sup>372</sup> CMS. QualityNet. IQR Measures—Web-Based Data Collection. Attestation Guide for the Maternal Morbidity Structural Measure. Available at: <https://qualitynet.cms.gov/inpatient/iqr/measures#tab2>.

<sup>373</sup> Academy of Nutrition and Dietetics. (2021). What is Malnutrition. Available at: <https://www.eatright.org/health/health-conditions/malnutrition-and-deficiencies/what-is-malnutrition>.



PCHs have an opportunity to identify malnutrition early in the patient admission process and to address it efficiently and effectively with interventions individualized to the patient's cancer treatment plan that could optimize outcomes, including reduced complications and lengths of stay.<sup>379</sup> However, gaps and inconsistencies exist in nutrition care practices in the inpatient setting,<sup>380</sup> and malnutrition remains poorly recognized, mostly due to a lack of awareness and inadequate coordination between healthcare providers.<sup>381</sup> The implementation of malnutrition care including: (1) malnutrition risk screening; (2) nutrition assessment following detection of malnutrition risk; (3) malnutrition diagnosis; and (4) nutrition care plans for patients identified as malnourished improves the identification and treatment of malnourished patients.<sup>382</sup> Providing inpatient nutritional support saves an estimated \$2,818 per patient over 6 months, largely due to fewer infections and shorter hospital stays.<sup>383</sup>

<sup>379</sup> PDQ® Supportive and Palliative Care Editorial Board. PDQ Nutrition in Cancer Care. Bethesda, MD: National Cancer Institute. Updated 09/20/2024. Available at: <https://www.cancer.gov/about-cancer/treatment/side-effects/appetite-loss/nutrition-hp-pdq>.

<sup>380</sup> Wills-Gallagher J, Kerr KW, Macintosh B, Valladares AF, Kilgore KM, Sulo S. (2022). Implementation of malnutrition quality improvement reveals opportunities for better nutrition care delivery for hospitalized patients. *Journal of Parenteral and Enteral Nutrition*, 46(1), 243–248. <https://doi.org/10.1002/jpen.2086>.

<sup>381</sup> Kabashneh S, Alkassis S, Shanah L, Ali H. (2020). A Complete Guide to Identify and Manage Malnutrition in Hospitalized Patients. *Cureus*, 12(6). <https://doi.org/10.7759/cureus.8486>.

<sup>382</sup> Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, McCauley S. (2021). How a Malnutrition Quality Improvement Initiative Furthers Malnutrition Measurement and Care: Results From a Hospital Learning Collaborative. *Journal of Parenteral and Enteral Nutrition*, 45(2), 366–371. <https://doi.org/10.1002/jpen.1833>.

<sup>383</sup> Schuetz P, Sulo S, Walzer S, Vollmer L, Brunton C, Kaegi-Braun N, Stanga Z, Mueller B, Gomes F. (2021). Cost savings associated with nutritional support in medical inpatients: an economic model based on data from a systematic review of randomised trials. *BMJ Open*, 11(7), e046402. <https://doi.org/10.1136/bmjopen-2020-046402>.

## (2) Overview of Measure

The Malnutrition Care Score eCQM assesses the percentage of adults aged 18 years and older at the start of the eligible encounter, with a length of stay equal to or greater than 24 hours, who received optimal malnutrition care appropriate to the specific patient's level of malnutrition risk and severity. Best practices related to the prevention and care of malnutrition recommend that for each eligible encounter, adult inpatients are: (1) screened for malnutrition risk or for a dietitian referral order to be placed; (2) assessed by a registered dietitian (RD) or registered dietitian nutritionist (RDN) to confirm findings of malnutrition risk, and if identified with a “moderate” or “severe” malnutrition status in the current performed nutrition assessment; (3) receive a “moderate” or “severe” malnutrition diagnosis by a physician or eligible clinician as defined by CMS; and (4) have a current nutrition care plan performed by an RD/RDN.<sup>384 385</sup>

To improve clinical outcomes for patients and reduce health care costs, we adopted the Malnutrition Care Score eCQM (previously known as the Global Malnutrition Composite Score eCQM) into the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs as one of the eCQMs that hospitals can select to report beginning with the CY 2024 reporting period (87 FR 49239 through 49246 and 87 FR 49361 through 49365, respectively). In the FY 2025 IPPS/LTCH PPS final rule, we modified the measure to include patients 18 years old and older in the measure cohort (89 FR

<sup>384</sup> Malnutrition Quality Improvement Initiative. (2024). MQii Toolkit. Available at: [https://malnutritionquality.org/mqii-toolkit/#case\\_malnutrition\\_care\\_hospital](https://malnutritionquality.org/mqii-toolkit/#case_malnutrition_care_hospital).

<sup>385</sup> Silver HJ, Pratt KJ, Bruno M, Lynch J, Mitchell K, McCauley SM. (2018). Effectiveness of the Malnutrition Quality Improvement Initiative on Practitioner Malnutrition Knowledge and Screening, Diagnosis, and Timeliness of Malnutrition-Related Care Provided to Older Adults Admitted to a Tertiary Care Facility: A Pilot Study. *Journal of the Academy of Nutrition and Dietetics*, 118(1):101–109. <https://doi.org/10.1016/j.jand.2017.08.111>.

69557 through 69560 and 89 FR 69621 through 69623). In this rule, we are also proposing mandatory reporting of the Malnutrition Care Score eCQM in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs beginning with the CY 2028 reporting period. We refer interested readers to sections IX.C.8.c.(2). and IX.F.9.c. of the preamble of this proposed rule for further discussion of this proposal in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs, respectively.

## (3) Measure Calculation

The Malnutrition Care Score eCQM consists of four components, which are scored separately: (1) screening for malnutrition risk at admission; (2) completing a nutrition assessment for patients who screened for risk of malnutrition; (3) appropriate documentation of malnutrition diagnosis in the patient's medical record if a malnutrition risk of “moderate” or “severe” was indicated by the assessment findings; and (4) development of a nutrition care plan for malnourished patients including the recommended treatment plan. The malnutrition components are specified for use in electronic health records (EHRs). The Malnutrition Care Score eCQM numerator is comprised of four components that are individually scored at the encounter level for patients 18 years of age and older who are admitted to a PCH. Each eligible component is given a value of 0 if not documented, or 1 if documented, and then all values are summed to total the numerator. The measure denominator is the total eligible occurrences of the four components for patients aged 18 years and older who are admitted to a PCH. The only denominator exclusion for this measure population is patients whose length of stay is less than 24 hours. Details on the cohort for each component are specified in Table IX.D.1.

**TABLE IX.D.1. MALNUTRITION CARE SCORE ECQM COMPONENT COHORT DESCRIPTIONS**

| Component                                                                                          | Numerator                                                                                      | Denominator                                                                                                                                                             |
|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Completion of a Malnutrition Screening                                                             | Patients in the denominator who have a malnutrition screening documented in the medical record | Patients age 18 years and older at time of admission who are admitted to a PCH                                                                                          |
| Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition           | Patients in the denominator who have a nutrition assessment documented in the medical record   | Patients age 18 years and older at time of admission who are admitted to a PCH and were identified as at-risk for malnutrition upon completing a malnutrition screening |
| Appropriate Documentation of a Malnutrition Diagnosis                                              | Patients in the denominator with a diagnosis of malnutrition documented in the medical record  | Patients age 18 years and older at time of admission who are admitted to a PCH with findings of malnutrition upon completing a nutrition assessment                     |
| Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment | Patients in the denominator who have a nutrition care plan documented in the medical record    | Patients age 18 years and older at time of admission who are admitted to a PCH with findings of malnutrition upon completing a nutrition assessment.                    |

The score for each eligible encounter is calculated by dividing the numerator by the denominator. Results range from 0 to 100 percent, with higher percentages indicating better performance. The measure specifications for the Malnutrition Care Score eCQM can be found on the Electronic Clinical Quality Improvement (eCQI) Resource Center website, available at: <https://ecqi.healthit.gov/eh-cah/ecqm-resources>.

#### (4) Pre-Rulemaking Process and Measure Endorsement

##### (a) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement website for details on the Pre-Rulemaking Measure Review process convened by the consensus-based entity (CBE), including the voting procedures used to reach consensus on measure recommendations.<sup>386 387</sup> The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available “2025 Measures Under Consideration List,” including the

Malnutrition Care Score eCQM (MUC2025–065).<sup>388</sup>

The voting results of the Recommendation Group for the proposed inclusion of the Malnutrition Care Score eCQM in the PCH Quality Reporting Program were: 19 members (95 percent) recommended adopting the measure into the PCH Quality Reporting Program, and one member (5 percent) voted not to recommend the measure for adoption.<sup>389</sup> With 95 percent of the votes for recommend, the Recommendation Group reached consensus agreement to recommend the Malnutrition Care Score eCQM for use in the PCH Quality Reporting Program.

The Pre-Rulemaking Measure Review Hospital Committee overall agreed that this measure is particularly relevant for cancer patients, who often experience malnutrition. The Recommendation Group member who voted not to recommend the measure expressed concerns that (1) rural hospitals often lack sufficient registered dietitian staffing, even with telemedicine, and (2) whether documenting screening leads to meaningful improvements in post-discharge outcomes.

In response to the Recommendation Group member's first concern about rural hospitals, the hospitals participating in the PCH Quality Reporting Program consist of 11 total PCHs. All PCHs are affiliated with large academic medical centers, research institutions, or standalone premier

cancer centers.<sup>390</sup> As there are no PCHs currently designated as rural hospitals or considered to be low-resource hospitals, this concern is not relevant to our proposal to adopt the Malnutrition Care Score eCQM into the PCH Quality Reporting Program.

Regarding the Recommendation Group member's second concern about meaningful improvements, the Malnutrition Care Score eCQM measure was endorsed in the Spring 2024 review cycle with a condition for the measure steward to review implementation data to examine whether the measure is associated with improved nutritional status or related clinical endpoints when the measure returns for maintenance review in the Spring 2029 cycle.<sup>391 392</sup> The measure developer is working to collect and review hospital implementation data to assess the clinical outcomes associated with the measure by its next review cycle in Spring 2029, and we will continue to evaluate the measure as more data is received.

We thank the committee for their recommendations and concerns. After taking them into consideration, we propose to adopt the Malnutrition Care Score eCQM in the PCH Quality Reporting Program beginning with the FY 2030 program year.

<sup>386</sup> Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. Available at: <https://p4qm.org/prmr/about>.

<sup>387</sup> In 2025, the CBE updated the Pre-Rulemaking Measure Review voting process such that committee members will vote to either “recommend” or “do not recommend” that a measure be added to the intended CMS program(s), thus, removing the “recommend with conditions” voting option. The threshold to reach consensus on a given measure continues to be a minimum of 75 percent agreement among members. Committee members can provide considerations for CMS to review prior to implementation.

<sup>388</sup> Centers for Medicare & Medicaid Services. 2025 Measures Under Consideration List. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview>.

<sup>389</sup> Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

<sup>390</sup> Centers for Medicare & Medicaid Services. PPS-Exempt Cancer Hospitals. Available at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/pps-exempt-cancer-hospitals-pchs>.

<sup>391</sup> Partnership for Quality Management. Malnutrition Care Score. Available at: <https://p4qm.org/measures/3592e>.

<sup>392</sup> Partnership for Quality Management. Spring 2024 Cycle Endorsement and Maintenance Technical Report Initial Recognition and Management. Available at: <https://p4qm.org/sites/default/files/Initial%20Recognition%20and%20Management/material/EM-Spring-2024-IRM-Final-Project-Report.pdf>.

## (b) Measure Endorsement

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The Malnutrition Care Score eCQM was recently reviewed by the Endorsement and Maintenance Initial Recognition and Management Committee as part of measure

maintenance in the Spring 2024 review cycle. The Endorsement and Maintenance committee voted to endorse with conditions. The condition was for the measure steward to review implementation data (including the recently expanded cohort of patients 18 years and older) to examine whether the measure is associated with improved nutritional status or related clinical endpoint when the measure returns for maintenance review in the Spring 2029 cycle.<sup>393 394</sup> We are working with the measure steward to collect and review hospital implementation data to assess

the clinical outcomes associated with the Malnutrition Care Score eCQM.

## (5) Data Sources, Submission, and Reporting

The Malnutrition Care Score eCQM uses data collected through a hospital's EHR. The measure is designed to be calculated by certified health information technology (IT) using the patient-level data and then submitted by the PCH to CMS. Table IX.D.2. outlines the data specification(s) and data sources for each of the four components.

**TABLE IX.D.2. MALNUTRITION CARE SCORE ECQM COMPONENTS AND DATA SOURCES**

| Component                                                                                          | Description                                                                                                                                                               | Data Sources                                                                                                                                                                                                                                                                                                              |
|----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Completion of a Malnutrition Screening                                                             | Patients age 18 years and older who were screened for malnutrition                                                                                                        | <ul style="list-style-type: none"> <li>- Inpatient Admission Time</li> <li>- Inpatient Discharge Time</li> <li>- Birthdate</li> <li>- Completed Malnutrition Screening</li> <li>- Completed Malnutrition Screening Time Stamp</li> </ul>                                                                                  |
| Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition           | Patients age 18 years and older identified as at-risk for malnutrition based on a malnutrition screening who have a nutrition assessment documented in the medical record | <ul style="list-style-type: none"> <li>- Inpatient Admission Time</li> <li>- Inpatient Discharge Time</li> <li>- Birthdate</li> <li>- Completed Malnutrition Screening</li> <li>- Malnutrition Screening Result</li> <li>- Completed Nutrition Assessment</li> <li>- Completed Nutrition Assessment Time Stamp</li> </ul> |
| Appropriate Documentation of a Malnutrition Diagnosis                                              | Patients age 18 years and older and found to be malnourished based on a completed nutrition assessment who have documentation of a malnutrition diagnosis                 | <ul style="list-style-type: none"> <li>- Inpatient Admission Time</li> <li>- Inpatient Discharge Time</li> <li>- Birthdate</li> <li>- Completed Nutrition Assessment</li> <li>- Nutrition Assessment Result</li> <li>- Malnutrition Diagnosis</li> </ul>                                                                  |
| Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment | Patients age 18 years and older and found to be malnourished based on a completed nutrition assessment who have a documented nutrition care plan in the medical record    | <ul style="list-style-type: none"> <li>- Inpatient Admission Time</li> <li>- Inpatient Discharge Time</li> <li>- Birthdate</li> <li>- Completed Nutrition Assessment</li> <li>- Nutrition Assessment Result</li> <li>- Documented Nutrition Care Plan</li> </ul>                                                          |

We propose to adopt the Malnutrition Care Score eCQM in the PCH Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 program year. We refer readers to section IX.D.5.b. of this proposed rule for a discussion of proposed form, manner, and timing of data submission and reporting requirements for eCQMs in the PCH Quality Reporting Program.

Section 1866(k)(4) of the Act requires the Secretary to make quality measure information available to the public after PCHs have the opportunity to review their data. If adoption of the Malnutrition Care Score eCQM is finalized, we propose to publicly report data as soon as it is feasible on CMS websites such as the Compare tool on

Medicare.gov (<https://www.medicare.gov/care-compare/>) and the CMS Provider Data Catalog or their successor websites after a 30-day preview period.

We invite public comment on our proposal to adopt the Malnutrition Care Score eCQM into the PCH Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 program year.

### 3. Proposed Removal in the PCH Quality Reporting Program Measure Set

#### a. Proposed Removal of the COVID-19 Vaccination Coverage Among Healthcare Personnel Measure

We refer readers to the FY 2022 IPPS/LTCH PPS final rule where we adopted the COVID-19 Vaccination Coverage

among Healthcare Personnel (HCP) measure (hereafter referred to as HCP COVID-19 Vaccination measure) into the PCH Quality Reporting Program (86 FR 45428 through 45434) and the FY 2024 IPPS/LTCH PPS final rule where we modified the HCP COVID-19 Vaccination measure to account for updated COVID-19 vaccine guidance (88 FR 59137 through 59144). The HCP COVID-19 Vaccination measure requires PCHs to report the COVID-19 vaccination status of HCP through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). PCHs must collect current vaccination status for all employees, licensed independent practitioners, adult trainees, students,

<default/files/Initial%20Recognition%20and%20Management/material/EM-Spring-2024-IRM-Final-Project-Report.pdf>.

<sup>393</sup> Partnership for Quality Management. Malnutrition Care Score. Available at: <https://p4qm.org/measures/3592e>.

<sup>394</sup> Partnership for Quality Management. Spring 2024 Cycle Endorsement and Maintenance Technical Report Initial Recognition and Management. Available at: <https://p4qm.org/sites/>

and volunteers, as well as certain contract personnel one week out of each month and report these data on a quarterly basis (88 FR 59140).

We propose to remove the HCP COVID-19 Vaccination measure beginning with the CY 2026 reporting period/FY 2028 program year under removal factor 2, a measure does not align with current clinical guidelines or practice (§ 412.24(d)(3)(i)(B)). When we originally adopted this measure, the United States was in the midst of a Public Health Emergency (PHE) with millions of COVID-19 cases and over 550,000 COVID-19 deaths (86 FR 45428). In March 2021, when this measure was being proposed, the United States was averaging over 5,000 deaths per week. In April 2023, the last full month of the PHE, the weekly number of deaths due to COVID-19 averaged around 1,300.<sup>395</sup> While preventing the spread of COVID-19 remains a public health goal, the PHE ended on May 11, 2023,<sup>396</sup> and the COVID-19 death rate has continued to decrease. The weekly number of deaths attributed to COVID-19 during the past 6 months (weeks ending 8/2/25 through 1/31/26) ranged from 188 to 498.<sup>397</sup>

With the end of the PHE and decrease in COVID-19 deaths, we believed the continued costs and burden to providers of reporting on this measure outweighed the benefit of continued information collection on HCP COVID-19 Vaccination in several settings. We have already removed this measure from the Hospital Inpatient Quality Reporting Program (90 FR 37010 through 37012), the Inpatient Psychiatric Facility Quality Reporting Program (90 FR 37657

through 37658), the Inpatient Rehabilitation Facility Quality Reporting Program (90 FR 37701 through 37702), the Ambulatory Surgical Center Quality Reporting Program (90 FR 53917 through 53919), and the Hospital Outpatient Quality Reporting Program (90 FR 53917 through 53919).

Since the end of the PHE, the CDC's clinical recommendations for COVID-19 vaccination have changed. In December 2020, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should receive a complete vaccination course.<sup>398</sup> At the time the HCP COVID-19 Vaccination measure was adopted in August 2021, vaccination was a critical part of the nation's strategy to effectively counter the spread of COVID-19 in an effort to restore societal functioning.<sup>399</sup> There were well-defined parameters for receiving the COVID-19 vaccination intended to capture routine, catch-up, and risk-based immunization recommendations.

However, these parameters no longer apply, due to evolving circumstances. The latest CDC COVID-19 vaccination recommendations for the 2025–2026 season are now based on shared clinical decision-making.<sup>400</sup> For shared clinical decision-making, there is not a default decision to vaccinate for a defined population.<sup>401</sup> Given that there is no

single default recommendation to vaccinate a defined population, both receipt and nonreceipt of vaccination may be consistent with the application of shared clinical decision-making. This differs from the guidance in place when this measure was finalized.

On this basis, we propose to remove the measure from the PCH Quality Reporting Program under removal Factor 2, a measure does not align with current clinical guidelines or practice. We refer readers to section IX.E.3. of this proposed rule for a similar proposal to remove the HCP COVID-19 Vaccination measure in the LTCH Quality Reporting Program.

If finalized, PCHs would not be required to report CY 2026 HCP COVID-19 Vaccination measure data for purposes of the FY 2028 program year. Any CY 2026 HCP COVID-19 vaccination data received by CMS would not be used for PCH Quality Reporting Program public reporting.

We invite public comment on our proposal to remove the COVID-19 Vaccination Coverage among Healthcare Personnel measure from the PCH Quality Reporting Program beginning with the CY 2026 reporting period/FY 2028 program year.

#### 4. Summary of Previously Finalized and Newly Proposed PCH Quality Reporting Program Measures

Table IX.D.3. summarizes the previously finalized and newly proposed PCH Quality Reporting Program measure set for the FY 2028 to FY 2031 program years. We propose to remove the COVID-19 Vaccination Coverage among HCP measure as discussed in section IX.D.3.a. of this proposed rule, add the Advance Care Planning eCQM as discussed in section IX.B.1. of this proposed rule and add the Malnutrition Care Score eCQM as discussed in section IX.D.2.a. of this proposed rule.

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[www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html](https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html).

<sup>395</sup> Centers for Disease Control and Prevention. Provisional COVID-19 Deaths, by Week, in The United States, Reported to CDC. Available at: [https://covid.cdc.gov/covid-data-tracker/#trends\\_weeklydeaths\\_select\\_00](https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00).

<sup>396</sup> U.S. Department of Health and Human Services. COVID-19 Public Health Emergency. Available at: <https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html>.

<sup>397</sup> Centers for Disease Control and Prevention. Provisional COVID-19 Mortality Surveillance. Available at: <https://www.cdc.gov/nchs/nvss/vsrr/covid19/>.

<sup>398</sup> Dooling K, McClung M, Chamberland M, Marin M, Wallace M, Bell B, Lee GM, Talbot HK, Romero JR, Oliver SE. (2020). "The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID-19 Vaccine—United States, 2020." *Morbidity and Mortality Weekly Report*, 69(49): 1857–1859. <http://dx.doi.org/10.15585/mmwr.mm6949e1>.

<sup>399</sup> Centers for Disease Control and Prevention. (2020). COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. Available at: [https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim\\_Playbook.pdf](https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf).

<sup>400</sup> Centers for Disease Control and Prevention. (2025). 2025–2026 COVID-19 Vaccination Guidance Available at: <https://www.cdc.gov/covid/hcp/vaccine-considerations/routine-guidance.html>.

<sup>401</sup> Centers for Disease Control and Prevention. (2025). ACIP Shared Clinical Decision-Making Recommendations. Available at: <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html>.

**TABLE IX.D.3. PREVIOUSLY FINALIZED AND NEWLY PROPOSED PCH QUALITY REPORTING PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND PROGRAM YEAR (PY)**

| Measure Name                                                                                                                                                                                                                                         | CBE Number | FY 2028 PY | FY 2029 PY | FY 2030 PY | FY 2031 PY |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------|------------|------------|------------|
| <b>NHSN Safety and Healthcare-Associated Infection (HAI) Measures</b>                                                                                                                                                                                |            |            |            |            |            |
| NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure                                                                                                                                                                             | 0138       | ✓          | ✓          | ✓          | ✓          |
| NHSN Central line-associated Bloodstream Infection (CLABSI) Outcome Measure                                                                                                                                                                          | 0139       | ✓          | ✓          | ✓          | ✓          |
| Influenza Vaccination Coverage Among Healthcare Personnel (HCP)                                                                                                                                                                                      | 0431       | ✓          | ✓          | ✓          | ✓          |
| COVID-19 Vaccination Coverage among HCP*                                                                                                                                                                                                             | N/A        |            |            |            |            |
| American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery) | 0753       | ✓          | ✓          | ✓          | ✓          |
| NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure                                                                                                                     | 1716       | ✓          | ✓          | ✓          | ✓          |
| NHSN Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure                                                                                                                                             | 1717       | ✓          | ✓          | ✓          | ✓          |
| Patient Safety Structural Measure                                                                                                                                                                                                                    | N/A        | ✓          | ✓          | ✓          | ✓          |
| <b>Claims-Based End-of-Life Measures</b>                                                                                                                                                                                                             |            |            |            |            |            |
| Proportion of Patients Who Died from Cancer - Receiving Chemotherapy in the Last 14 Days of Life                                                                                                                                                     | 0210       | ✓          | ✓          | ✓          | ✓          |
| Proportion of Patients Who Died from Cancer - Not Admitted to Hospice                                                                                                                                                                                | 0215       | ✓          | ✓          | ✓          | ✓          |
| Proportion of Patients Who Died from Cancer - Admitted to the ICU in the Last 30 Days of Life                                                                                                                                                        | 0213       | ✓          | ✓          | ✓          | ✓          |
| Proportion of Patients Who Died from Cancer - Admitted to Hospice for Less Than Three Days                                                                                                                                                           | 0216       | ✓          | ✓          | ✓          | ✓          |
| <b>Patient Engagement/Experience of Care Measures</b>                                                                                                                                                                                                |            |            |            |            |            |
| Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey                                                                                                                                                                     | 0166       | ✓          | ✓          | ✓          | ✓          |
| Documentation of Goals of Care Discussions Among Cancer Patients                                                                                                                                                                                     | N/A        | ✓          | ✓          | ✓          | ✓          |
| <b>Claims-Based Outcome Measures</b>                                                                                                                                                                                                                 |            |            |            |            |            |
| Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy                                                                                                                                                       | N/A        | ✓          | ✓          | ✓          | ✓          |
| 30-Day Unplanned Readmissions for Cancer Patients                                                                                                                                                                                                    | 3188       | ✓          | ✓          | ✓          | ✓          |
| Surgical Treatment Complications for Localized Prostate Cancer                                                                                                                                                                                       | N/A        | ✓          | ✓          | ✓          | ✓          |
| <b>Electronic Clinical Quality Measures</b>                                                                                                                                                                                                          |            |            |            |            |            |
| Advance Care Planning eCQM**                                                                                                                                                                                                                         | N/A        |            |            | ✓          | ✓          |
| Malnutrition Care Score eCQM**                                                                                                                                                                                                                       | 3592e      |            |            | ✓          | ✓          |

✓ Measure required for the specified program year

\*Proposed for removal in this proposed rule beginning with the CY 2026 reporting period/FY 2028 program year.

\*\*Proposed for adoption in this proposed rule beginning with the CY 2028 reporting period/FY 2030 program year.

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We refer readers to the CMS QualityNet website at <https://qualitynet.cms.gov/pch> for additional information on the reporting periods and submission deadlines for each measure previously finalized in the PCH Quality Reporting Program.

#### 5. Proposed Updates to the Form, Manner, and Timing of Quality Data Submission

We propose to update program policies for introducing eCQMs into the PCH Quality Reporting Program by establishing eCQM data submission and reporting requirements, which would apply to the proposed Advance Care

Planning eCQM and Malnutrition Care Score eCQM.

#### a. Maintenance of Technical Specifications for Quality Measures

Section 412.24(c) of title 42 of the Code of Federal Regulations generally requires that a PCH participating in the PCH Quality Reporting Program must submit to CMS data on measures selected under section 1833(k)(3) of the Act in a form and manner, and at a time, specified by CMS. The data submission requirements, specifications manual, measure methodology reports, and submission deadlines are posted on the QualityNet website at: <https://qualitynet.cms.gov>

(or other successor CMS designated websites).

In alignment with the Hospital Inpatient Quality Reporting Program, we propose that the technical specifications for eCQMs for the PCH Quality Reporting Program would be contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). The Annual Update and implementation guidance documents are available on the eCQI Resource Center website at: <https://ecqi.healthit.gov/>. For eCQMs, we would generally update the measure specifications on an annual basis through the Annual Update process which includes code updates, logic

corrections, alignment with current clinical guidelines, and additional guidance for PCHs and EHR vendors to collect and submit data on eCQMs from EHRs. In addition, we would generally update related eCQM implementation guidance on an annual basis. We propose that PCHs would be required to use the eCQM electronic measure specifications and implementation guidance for the applicable reporting period available on the eCQI Resource Center website at: <https://ecqi.healthit.gov/> or another website as designated by CMS.

We invite public comment on this proposal.

#### b. Proposed Data Submission and Reporting Requirements for Electronic Clinical Quality Measures for the PCH Quality Reporting Program

##### (1) Background

Collection and reporting of data through health IT streamlines quality reporting through automated electronic extraction and reporting. Certified health IT assists facilities in a variety of ways, such as by improving coordination of care with referring providers or labs,<sup>402</sup> using eCQMs to improve quality and safety, and advancing a vision to eventually transition to a fully digital quality measure set.<sup>403</sup> We acknowledge the initial investment that the implementation of eCQMs may require for PCHs, but we expect that this investment will deliver long-term burden reduction along with more accurate and timely access to quality information to inform patient care.

We intend to transition to a fully digital quality measure (dQM) landscape, first by transitioning eCQMs to Health Level 7® Fast Healthcare Interoperability Resources® (FHIR®)-based eCQMs, to promote interoperability and increase the value of quality measure data.<sup>404</sup> While we continue to transition our quality measurement infrastructure to dQMs, we are advancing interim improvements by expanding the use of eCQMs in our

quality reporting programs. This approach will promote meaningful progress in electronic quality measurement while supporting deliberate, phased conversion to FHIR and dQMs over time. We refer readers to our most recent request for information on the transition to digital quality measurement (90 FR 36990 through 36996) for more information.

We refer readers to sections IX.B.1. and IX.D.2.a. of the preamble of this proposed rule, where we propose to adopt the Advance Care Planning eCQM and the Malnutrition Care Score eCQM, respectively, into the PCH Quality Reporting Program measure set for a full year of reporting beginning with the CY 2028 reporting period/FY 2030 program year. If our proposals are finalized, the Advance Care Planning eCQM and the Malnutrition Care Score eCQM would be the first eCQMs in the PCH Quality Reporting Program; although, CMS began providing hospitals with the opportunity to voluntarily submit eCQM data in CY 2013 before required reporting in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs in CY 2016. Additionally, eCQMs are used in the Hospital Outpatient Quality Reporting Program, Rural Emergency Hospital (REH) Quality Reporting Program, Merit-Based Incentive Payment System for clinicians, and certain CMS Innovation Center models.

Introducing eCQM reporting in the PCH Quality Reporting Program involves establishing related policies and requirements, including eCQM certification requirements, data standards and formats, submission methods, and other program-specific requirements. In the following sections, we propose eCQM submission and reporting requirements for the PCH Quality Reporting Program that align with these other programs.

##### (2) Proposed eCQM Reporting and Data Submission Requirements

###### (a) Certification Requirements for eCQM Reporting

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69569) and the CY 2025 OPPI/ASC final rule (89 FR 94418 through 94420), we summarized our requirements with respect to using technology meeting the Office of the National Coordinator for Health Information Technology's (ONC) health IT certification criteria for reporting eCQMs in the Hospital Inpatient Quality Reporting Program and the Hospital Outpatient Quality Reporting Program, respectively. We propose to adopt similar eCQM certification requirements

in the PCH Quality Reporting Program, and to codify them by adding a new paragraph (g) "Requirements for submission of electronic clinical quality measures (eCQMs) under the PCHQR Program" to 42 CFR 412.24.

Under this approach, we propose to codify at § 412.24(g)(1) the requirement for PCHs to utilize health IT certified to the ONC Health IT Certification Program certification criteria, as adopted and updated at 45 CFR 170.315(c), which cover the elements necessary for eCQM reporting under the PCH Quality Reporting Program.

We also propose to codify at 42 CFR 412.24(g)(2) the requirement that PCHs use the certified health IT described in paragraph (g)(1) to calculate, export, and submit results for the eCQMs available to report under the PCHQR Program. Additionally, we propose to codify at § 412.24(g)(3) the requirement that PCHs use the eCQM electronic measure specifications for the applicable reporting period available on the eCQI Resource Center website at: <https://ecqi.healthit.gov/> or another website as designated by CMS. Further, consistent with the other programs, we propose that health IT would not need to be recertified each time the eCQMs' specifications are updated to a more recent version. Under this proposal, this requirement would apply beginning with the CY 2028 reporting period/FY 2030 program year and for subsequent years. Any substantive changes to modernize electronic submission methods would be proposed in future rulemaking.

###### (b) File Format for eCQM Reporting

When EHRs and health IT systems capture data in standardized formats, the information is represented and interpreted consistently, enabling automated computation without manual interpretation. As described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701), these standards are referred to as content exchange standards because the standards detail how data should be represented and the relationships between data elements. This allows the data to be exchanged across EHRs and health IT systems while retaining their meaning. At this time, the Quality Reporting Document Architecture (QRDA) standard is the standard file format used for eCQM submission in CMS quality programs that rely on QRDA-based eCQM reporting. The QRDA standard provides a document format and standard structure to electronically report quality measure data, promotes consistent representation of the data, and enables calculation of eCQM measure results.

<sup>402</sup> Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT (May 2024). Interoperable Exchange of Patient Health Information Among U.S. Hospitals: 2023. Available at: <https://www.healthit.gov/data/data-briefs/interoperable-exchange-patient-health-information-among-us-hospitals-2023>.

<sup>403</sup> Centers for Medicare & Medicaid Services. Electronic Clinical Quality Improvement (eCQI) Resource Center. Available at: <https://ecqi.healthit.gov/>.

<sup>404</sup> For more information on dQMs, visit: <https://ecqi.healthit.gov/dqm/about-dqms>.

<sup>405</sup> FHIR® is the registered trademark of Health Level Seven International (HL7), and its use does not constitute endorsement by HL7.

To utilize the same file format requirements currently applied in the Hospital Inpatient Quality Reporting Program (85 FR 58940), the Hospital Outpatient Quality Reporting Program (86 FR 63869), the REH Quality Reporting Program (90 FR 53954), and the Medicare Promoting Interoperability Program (80 FR 49706), we propose comparable file format requirements for the PCH Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 program year. Specifically, we propose that a PCH: (1) must submit eCQM data via the QRDA Category I (QRDA I) file format;<sup>406</sup> (2) may use third parties to submit QRDA I files on their behalf;<sup>407</sup> and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into certified health IT for capture and reporting in the QRDA I file format. Under this proposal, we expect QRDA I files to reflect data for one patient per file per quarter with five key elements necessary to identify the file: (1) CCN; (2) CMS Program Name; (3) EHR Patient ID; (4) Reporting period specified in the Reporting Parameters Section; and (5) EHR Submitter ID. For technical guidance in implementing these standards for quality reporting, we refer readers to the QRDA Implementation Guides available at: <https://ecqi.healthit.gov/qrda/versions>.

In addition, we propose that a PCH could meet the eCQM reporting requirements by submitting data via QRDA I files, submitting a zero-denominator declaration, or submitting a case threshold exemption. We discuss the zero-denominator declaration and case threshold exemptions in the subsequent sections. We also refer readers to section IX.D.5.a. of this proposed rule where we outline the maintenance of technical specifications including those for eCQMs.

#### (c) Zero Denominator Declarations

We understand there may be situations in which a PCH does not have data to report on a particular eCQM. Therefore, we propose that if the PCH's health IT is certified to an eCQM but the PCH does not have patients that meet the denominator criteria of that eCQM, the PCH would submit a zero in the denominator for that eCQM. Submission

of a zero in the denominator for such an eCQM would qualify as a successful submission for that eCQM.

#### (d) Case Threshold Exemptions

We understand that in some cases, a PCH may not meet the case threshold of discharges for a particular eCQM to reliably calculate performance on the measure. We propose to align with the case threshold exemption policy from the Medicare Promoting Interoperability Program (77 FR 54080), the Hospital Inpatient Quality Reporting Program (79 FR 50323 and 50324), the Hospital Outpatient Quality Reporting Program (86 FR 63869), and the REH Quality Reporting Program (90 FR 53954). As stated for the Hospital Inpatient Quality Reporting Program, the case threshold exemption means that for each quality measure where the minimum number of patients that meet the patient population denominator criteria for the relevant reporting period is not met, a hospital could declare a "case threshold exemption." We propose a PCH using certified health IT would be exempt from reporting on that eCQM if the PCH has 5 or fewer applicable inpatient encounters or discharges per quarter or 20 or fewer applicable inpatient encounters or discharges per year (Medicare and non-Medicare combined), with applicability defined by specifications for each eCQM's denominator population. Case threshold exemptions would be entered on the Denominator Declaration screen within CMS' Hospital Quality Reporting System available during the submission period. The exemption would not have to be used, and a PCH could report those individual cases if they elect to do so. However, the measure rate would not be publicly reported if below the case threshold. We propose to adopt the case threshold exemption for the PCH Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 program year.

#### (3) Proposed Submission Deadlines for eCQM Data

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57171 and 57172), the Hospital Inpatient Quality Reporting Program aligned its eCQM submission deadline with that of the Medicare Promoting Interoperability Program. The eCQM submission deadline we have established for those two programs is by the end of 2 months following the close of the calendar year reporting period.

To align with these existing programs, we propose to require eCQM data submission for the PCH Quality Reporting Program by the end of 2 months following the close of the

calendar year for the CY 2028 reporting period/FY 2030 program year and for subsequent years. We believe that by aligning with these existing programs' deadlines we can minimize burden and simplify understanding of the data reporting requirements. For example, for the CY 2028 reporting period/FY 2030 program year, a PCH would be required to submit eCQM data to CMS by February 28, 2029, which is the end of 2 months following the close of the calendar year (December 31, 2028). If this date falls on a weekend or Federal holiday, the submission deadline would be moved to the next business day under established reporting practices.

We invite public comment on these eCQM submission and reporting proposals.

#### c. Review and Corrections Period for eCQM Data Submitted to the PCH Quality Reporting Program

In alignment with the Hospital Inpatient Quality Reporting Program (86 FR 63870), we propose a review and corrections period for eCQM data which would run concurrently with the data submission period. The review and corrections period is from the time the submission period opens to the submission deadline. In the Hospital Quality Reporting System, providers can submit QRDA Category I test and production data files and can correct QRDA Category I test and production data files before production data are submitted for final reporting. We encourage early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting. The Hospital Quality Reporting System does not allow data to be submitted or corrected after the annual deadline. We refer readers to the Hospital Quality Reporting System website (available at: <https://hqr.cms.gov/hqrng/support>), the eCQI Resource Center (available at: <https://ecqi.healthit.gov/>), and the CMS QualityNet website (<https://qualitynet.cms.gov/pch/public-reporting>) for more resources on eCQM reporting, submission deadlines, and program notifications for the PCH Quality Reporting Program.

We invite public comment on our proposal.

#### E. Proposed Changes to the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

##### 1. Background and Statutory Authority

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals

<sup>406</sup> QRDA I is an individual patient-level quality report that contains quality data for one patient for one or more eCQMs. QRDA creates a standard method to report quality measure results in a structured, consistent format and can be used to exchange eCQM data between systems.

<sup>407</sup> The PCH remains responsible for ensuring the data submitted by a third party is true, accurate, and complete.

certified by Medicare as long-term care hospitals (LTCHs). Section 1886(m)(5)(C) of the Act requires LTCHs to submit to the Secretary quality measure data specified under section 1886(m)(5)(D) in a form and manner, and at a time, specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act, resource use or other measures under section 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. LTCHs must submit the data required under section 1886(m)(5)(F) of the Act in the form and manner, and at the time, specified by the Secretary. Section 1886(m)(5)(A) of the Act requires the Secretary to reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not submitted data to the Secretary in accordance with the LTCH QRP requirements specified for that fiscal year. Section 1890A of the Act

requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890(a) of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the LTCH QRP. We have codified our program requirements in our regulations at 42 CFR 412.560.

In this proposed rule, we are proposing the removal of two measures, specifically the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure and the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, beginning with the FY 2028 LTCH QRP as described in sections IX.E.3. and IX.E.4. of the preamble of this proposed rule. In section IX.E.6.b, of the preamble of this proposed rule, we are also proposing to revise the LTCH QRP Data Submission Deadlines beginning with the FY 2029 LTCH QRP. We are also soliciting public comments on one Request for Information (RFI) on future measure concepts for the LTCH QRP in section

IX.E.5 of the preamble of this proposed rule.

## 2. General Considerations Used for the Selection of Measures for the LTCH QRP—Quality Measures Currently Adopted for the LTCH QRP

For a detailed discussion of the considerations we use for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 Inpatient Prospective Payment System (IPPS)/LTCH PPS final rule (80 FR 49728). The LTCH QRP currently has 18 adopted measures, which are set out in Table IX.E.-01. We did not propose to adopt any new measures for the LTCH QRP.

For a discussion of the factors we use to evaluate whether a measure should be removed from the LTCH QRP, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634) and to the regulations at § 412.560(b)(3).

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**TABLE IX.E.-01: QUALITY MEASURES CURRENTLY ADOPTED FOR THE LTCH QRP**

| Short Name                                       | Measure Name & Data Source                                                                                                                                        |
|--------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>LTCH CARE Data Set</b>                        |                                                                                                                                                                   |
| Pressure Ulcer/Injury Application of Falls       | Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) |
| Change in Mobility                               | Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients requiring ventilator support                                         |
| DRR                                              | Drug Regimen Review Conducted with Follow-Up for Identified Issues—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)           |
| Compliance with SBT Ventilator Liberation        | Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay Ventilator Liberation Rate                                                            |
| TOI-Provider                                     | Transfer of Health Information to the Provider Post-Acute Care (PAC)                                                                                              |
| TOH-Patient                                      | Transfer of Health Information to the Patient Post-Acute Care (PAC)                                                                                               |
| DC Function                                      | Discharge Function Score                                                                                                                                          |
| Patient/Resident COVID-19 Vaccine                | COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date                                                                                                |
| <b>National Healthcare Safety Network (NHSN)</b> |                                                                                                                                                                   |
| CAUTI                                            | National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure                                                     |
| CLABSI                                           | National Healthcare Safety Network (NHSN) Central-Line associated Bloodstream Infection (CLABSI) Outcome Measure                                                  |
| CDI                                              | National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure                     |
| HCP Influenza Vaccine                            | Influenza Vaccination Coverage among Healthcare Personnel (HCP)                                                                                                   |
| HCP COVID-19 Vaccine                             | COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)                                                                                                    |
| <b>Claims-Based</b>                              |                                                                                                                                                                   |
| MSPB LTCH                                        | Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)                                     |
| DTC                                              | Discharge to Community—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)                                                       |
| PPR                                              | Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)                              |



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### 3. Proposal To Remove the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2028 LTCH QRP

We refer readers to the FY 2022 IPPS/LTCH PPS final rule where we adopted the COVID-19 Vaccination Coverage among HCP measure (HCP COVID-19 Vaccine measure) into the LTCH QRP (86 FR 45438 through 45446) and the FY 2024 LTCH PPS final rule where we modified the HCP COVID-19 Vaccine measure to account for updated COVID-19 vaccine guidance (88 FR 59138 through 59144). The HCP COVID-19 Vaccine measure requires LTCHs to report the COVID-19 vaccination status of HCP through the National Healthcare Safety Network (NHSN). LTCHs must collect current vaccination status for all employees, licensed independent practitioners, adult trainees, students, and volunteers, as well as certain contract personnel one week out of each month and report these data on a quarterly basis (88 FR 59139).

We are proposing to remove the HCP COVID-19 Vaccine measure beginning with the FY 2028 LTCH QRP under measure removal Factor 3; a measure does not align with current clinical guidelines or practice (§ 412.560(b)(3)(iii)). When we originally adopted this measure, the United States was in the midst of a Public Health Emergency (PHE) with millions of COVID-19 cases and over 550,000 COVID-19 deaths (88 FR 59138 and 59139). In March 2021, when this measure was being proposed, the United States was averaging over 5,000 deaths per week. In April 2023, the last full month of the PHE, the weekly number of deaths due to COVID-19 averaged around 1,300.<sup>408</sup> While preventing the spread of COVID-19 remains a public health goal, the PHE ended on May 11, 2023,<sup>409</sup> and the COVID-19 death rate has continued to decrease. The weekly number of deaths attributed to COVID-19 during the past 6 months (weeks ending 8/2/25 through 1/31/26) ranged from 188 to 488.<sup>410</sup>

With the end of the PHE and decrease in COVID-19 deaths, we believed the continued costs and burden to providers of reporting on this measure outweighed the benefit of continued information collection on the HCP COVID-19

Vaccine measure in several settings. We have already removed this measure from the Hospital Inpatient Quality Reporting Program (90 FR 37010 through 37012), the Inpatient Psychiatric Facility Quality Reporting Program (90 FR 37657 through 37658), the Ambulatory Surgical Center Quality Reporting (90 FR 53917 through 53919), the Hospital Outpatient Quality Reporting Programs (90 FR 53917 through 53919), and the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (90 FR 37700 through 37702).

Since the end of the PHE, the CDC's clinical recommendations for COVID-19 vaccination have changed. In December 2020, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should receive a complete vaccination course.<sup>411</sup> At the time the HCP COVID-19 Vaccine measure was adopted in August 2021, vaccination was a critical part of the nation's strategy to effectively counter the spread of COVID-19 in an effort to restore societal functioning.<sup>412</sup> There were well-defined parameters for receiving the COVID-19 vaccination intended to capture routine, catch-up, and risk-based immunization recommendations.

However, these parameters no longer apply, due to evolving circumstances. The latest CDC COVID-19 vaccination recommendations for the 2025-2026 season are now based on shared clinical decision-making (also known as individual-based decision-making).<sup>413</sup> For shared clinical decision-making, there is not a default decision to vaccinate for a defined population.<sup>414</sup> Given that there is no single default recommendation to vaccinate a defined population, both receipt and nonreceipt of vaccination may be consistent with the application of shared clinical decision-making. This differs from the guidance in place when this measure was finalized.

On this basis, we are proposing to remove the measure from the LTCH QRP under removal Factor 3, measure

does not align with current clinical guidelines or practice.

If finalized as proposed, LTCHs would not be required to report CY 2026 HCP COVID-19 Vaccine measure data for purposes of the FY 2028 payment determination (that is, LTCHs that do not report CY 2026 HCP COVID-19 vaccine measure data would not be penalized for FY 2028 annual payment update under the LTCH QRP). Any CY 2026 HCP COVID-19 vaccine data received by CMS would not be used for LTCH QRP compliance or public reporting.

We invite public comment on our proposal to remove the COVID-19 Vaccination Coverage among Healthcare Personnel measure from the LTCH QRP beginning with the FY 2028 LTCH QRP.

### 4. Proposal To Remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning With the FY 2028 LTCH QRP

We refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 59243 through 59250), where we finalized the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) measure for the FY 2026 LTCH QRP. The measure is an assessment-based process measure that reports the percent of stays in which patients in an LTCH are up to date on their COVID-19 vaccinations per the CDC's latest guidance. In the FY 2026 LTCH PPS final rule (90 FR 37033 through 90 FR 37034), we finalized a modification to the reporting requirements for this measure to exclude patients who expired in the LTCH beginning with the FY 2028 LTCH QRP.

We are proposing to remove the Patient/Resident COVID-19 Vaccine measure from the LTCH QRP beginning with the FY 2028 LTCH QRP under removal Factor 3: a measure does not align with current clinical guidelines or practice (§ 412.560(b)(3)(iii)).

When we originally adopted the Patient/Resident COVID-19 Vaccine measure, COVID-19 continued to be a major challenge for LTCHs, with older adults at a significantly higher risk of mortality, severe disease, and death following infection (88 FR 59243 and 59244). In August 2023, when this measure was adopted, CDC COVID-19 vaccination guidance emphasized population-level vaccination expectations for older adults and other high-risk groups, and the evidence base focused on demonstrating broad protective benefit at the population level. CDC data at that time showed that, among adults aged 50 years and older, individuals who had received a

<sup>408</sup> Provisional COVID-19 Deaths, by Week, in The United States, Reported to CDC. Accessed on March 27, 2025, via [https://covid.cdc.gov/covid-data-tracker/#trends\\_weeklydeaths\\_select\\_00](https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00).

<sup>409</sup> <https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html>.

<sup>410</sup> Provisional COVID-19 Mortality Surveillance <https://www.cdc.gov/nchs/nvss/vsrr/covid19/> <https://covid.cdc.gov/covid-data-tracker/>.

<sup>411</sup> Dooling, K, McClung, M, et al. "The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID-19 Vaccine—United States, 2020." *Morb. Mortal Wkly Rep.* 2020; 69(49): 1857–1859.

<sup>412</sup> Centers for Disease Control and Prevention. (2020). COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed March 6, 2026 at <https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim-Playbook.pdf>.

<sup>413</sup> 2025–2026 COVID-19 Vaccination Guidance 2025–2026 COVID-19 Vaccination Guidance | Covid | CDC.

<sup>414</sup> ACIP Shared Clinical Decision-Making Recommendations ACIP Shared Clinical Decision-Making Recommendations | ACIP | CDC.

primary vaccination series and booster dose experienced significantly lower risks of COVID-19-related hospitalization and death compared to those who were unvaccinated, and that additional booster doses, including bivalent booster formulations, further reduced the risk of severe outcomes, including hospitalization and death, in the context of emerging variants (88 FR 59244). These data supported an infection prevention framework under which being “up to date” with COVID-19 vaccination was treated as a broadly applicable expectation for high-risk populations and therefore appropriate for monitoring through a facility-level quality measure.

At the time the Patient/Resident COVID-19 Vaccine measure was adopted, it was intended to capture routine, catch-up, and risk-based immunization recommendations. Due to evolving circumstances, the latest CDC COVID-19 vaccination recommendations for the 2025–2026 season are now based on shared clinical decision-making (also known as individual-based decision-making).<sup>415</sup> For shared clinical decision-making, there is not a default decision to vaccinate for a defined population.<sup>416</sup> Given that there is no single default recommendation to vaccinate a defined population, both vaccination and non-vaccination may be consistent with application of shared clinical decision-making. This differs from the guidance in place when this measure was finalized.

When there were more narrow parameters for receiving the COVID-19 vaccination, the Patient/Resident COVID-19 Vaccine measure promoted consumer transparency and choice by giving consumers clear information on the number of patients in an LTCH who were vaccinated. However, these parameters no longer apply in light of current CDC clinical guidance that recommends shared clinical decision-making for COVID-19 vaccination decisions. As a result, both vaccination and non-vaccination may reflect an “up to date” status using the guidance of shared clinical decision-making, and the Patient/Resident COVID-19 Vaccine measure may no longer provide information on the prevalence of COVID-19 vaccination in the LTCH setting. On this basis, we are proposing to remove the measure from the LTCH QRP under removal Factor 3: a measure

does not align with current clinical guidelines or practice.

Removing this measure would bring LTCH in to alignment with other post-acute care settings since we have already removed this measure from the Home Health Quality Reporting Program (HH QRP) (90 FR 55416 through 55418) and the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (90 FR 37702 through 37704).

We are proposing that beginning with patients discharged on or after October 1, 2026, LTCHs would no longer be required to collect and submit the Patient/Resident COVID-19 Vaccine measure data to CMS. We are also proposing to remove the Patient’s COVID-19 vaccination is up to date data element (O0350) from the LCDS as of October 1, 2028, since it is not technically feasible to remove this data element earlier. However, under our proposal, this data element would become voluntary and LTCHs would not be required to collect and submit Patient/Resident COVID-19 Vaccine data beginning with patients discharged on or after October 1, 2026.

We invite public comment on our proposal to remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure from the LTCH QRP beginning with the FY 2028 LTCH QRP.

#### 5. LTCH QRP Measure Concepts Under Consideration for Future Years—Request for Information (RFI)

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27150 through 27153), we included a request for information (RFI) on a set of principles for selecting and prioritizing LTCH QRP measures, identifying measurement gaps and suitable measures for filling these gaps. We refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 59250 and 59251) for a summary of the public comments we received in response to the RFI.

We are seeking input on the importance, relevance, appropriateness, and applicability of the quality measure concept of advanced care planning for future years in the LTCH QRP. Advance care planning is a continuous process that supports people in understanding and communicating their goals, values, and preferences regarding future medical decisions.<sup>417</sup> The Patient Self Determination Act of 1990<sup>418</sup> supports

this process by requiring healthcare facilities to inform patients of their rights regarding medical decisions, including advance directives and end of life care.<sup>419</sup> In post-acute care (PAC) settings, where patients recover from acute illness, injury, or major procedures, their needs and goals may evolve as their condition changes. Factors such as clinical stability, functional status, therapy tolerance, cognition function, prognosis, and personal preferences can all shift during recovery. Regular reassessment and transparent communication are essential to maintaining person-centered care, while advance care planning facilitates shared decision-making by documenting patient preferences and ensuring goal-concordant care throughout care transitions.<sup>420</sup>

As we review new measure concepts, we will prioritize evidence-based outcome measures that promote person-centered care practices. We are seeking input on the relevant aspects of advanced care planning and measures appropriate for the LTCH setting.

#### 6. Form, Manner, and Timing of Data Submission Under the LTCH QRP

##### a. Background

We refer readers to the regulatory text at § 412.560(b) for information regarding the current policies for reporting specified data for the LTCH QRP.

##### b. Proposal To Revise LTCH QRP Data Submission Deadlines Beginning With the FY 2029 LTCH QRP

##### (1) Background

Sections 1886(m)(5)(E) and 1899B(f) and (g) of the Act require CMS to provide feedback to LTCHs and to publicly report their performance on quality and other measures specified under the LTCH QRP. More specifically, section 1899B(f)(1) of the Act requires the Secretary to provide confidential feedback reports to LTCHs on their performance on the quality, resource use, and other measures specified for the LTCH QRP. Section 1899B(f)(2) of the Act provides that, to the extent feasible, the Secretary must make these confidential feedback reports available not less frequently than on a quarterly basis, except in the case of measures reported on an annual basis, in which case the confidential feedback reports

<sup>415</sup> 2025–2026 COVID-19 Vaccination Guidance 2025–2026 COVID-19 Vaccination Guidance | Covid | CDC.

<sup>416</sup> ACIP Shared Clinical Decision-Making Recommendations ACIP Shared Clinical Decision-Making Recommendations | ACIP | CDC.

<sup>417</sup> McMahan, R.D., Tellez, I., & Sudore, R.L. (2021). Deconstructing the Complexities of Advance Care Planning Outcomes: What Do We Know and Where Do We Go? A Scoping Review. *Journal of the American Geriatrics Society*, 69(1), 234–244. <https://doi.org/10.1111/jgs.16801>.

<sup>418</sup> Pub. L. 101–508, sections 4206, 4751.

<sup>419</sup> <https://www.congress.gov/bill/101st-congress/house-bill/5835>.

<sup>420</sup> McMahan RD, Tellez I, Sudore RL. Deconstructing the Complexities of Advance Care Planning Outcomes: What Do We Know and Where Do We Go? A Scoping Review. *J Am Geriatr Soc*. 2021 Jan;69(1):234–244. doi: 10.1111/jgs.16801. Epub 2020 Sep 7. PMID: 32894787; PMCID: PMC7856112.

may be made available annually. Additionally, sections 1886(m)(5) and 1899B(g)(1) of the Act require the Secretary to provide for the public reporting of each LTCH's performance on the measures specified for the LTCH QRP by establishing procedures for making the performance data available to the public. Sections 1886(m)(5)(E) and 1899B(g)(2) of the Act specifically require that such procedures must ensure that LTCHs can review the data and other information before it is made public.

For LCDS assessment-based measures, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 and 53637), we finalized submission deadlines for LTCHs to submit data quarterly for each of the finalized measures in the FY 2013 rule, requiring LTCHs to submit data collected during each quarter for the FY 2015 payment determination approximately 4.5 months (135 days) after the end of the quarter. We also finalized in the FY 2013 rule that LTCHs would have a shorter data submission timeframe for each of the measures for the FY 2016 payment determination. Specifically, for each quarter in which data was collected for the FY 2016 payment determination, we finalized submission deadlines that were approximately 45 days after the end of each quarter (77 FR 53636 and 53637). However, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49749 through 49751), we finalized a requirement that LTCHs submit data within 4.5 months of the end of each calendar quarter, beginning with the FY 2017 LTCH QRP, unless otherwise specified for a measure. We proposed and finalized this modification to the LTCH QRP data submission deadlines in order to align with the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) and Hospital Inpatient Quality Reporting (IQR) Program (80 FR 49749 through 49751).

We also finalized data submission deadlines for LTCH QRP measures that are submitted via the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50882), we finalized that for the NHSN Catheter Associated Urinary Tract Infection (CAUTI), the NHSN Central Line-Associated Bloodstream Infection (CLABSI) and the Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measures, each facility's data must be entered into NHSN no later than 45 days after the end of the reporting quarter. However, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49749 through 49751), we finalized a requirement that LTCHs submit data within 4.5 months of the end of each calendar quarter for these measures. We also finalized that the data collection period for the Influenza Vaccination Coverage among Healthcare Personnel (HCP) measure would be October 1 through March 31, with a data submission deadline of May 15th for each influenza season (78 FR 50882 and 50883). In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59138), we finalized that the COVID-19 Vaccination Coverage among HCP measure would be reported to the CDC through the NHSN at least 1 week per month, with the CDC reporting data to CMS quarterly and allowing for corrections in the NHSN application in alignment with CMS data submission deadlines.

Public reporting of data collected under quality programs, such as the LTCH QRP, is designed to provide consumers and their families with the most current information to empower them to make quality-informed decisions about where to receive their care. We have identified that the time between when data on measures is submitted to us and when those data are publicly reported (approximately nine months) may be too long to provide the most accurate and up to date

information for the public. For example, through technical expert panels (TEPs), we have received feedback from patient caregiver advocates that the aged data used in publicly reported quality measures diminishes their value to consumers.

Currently, the largest contributing factor to the nine-month lag between the end of the data collection period and when measures are publicly reported is the 4.5-month timeframe for data submission. Reducing the data submission timeframe from 4.5 months to 45 days could reduce this lag by up to three months, resulting in more timely public reporting of data for consumers and increasing the value of publicly reported data. Additionally, this timeframe provides LTCHs with more recent data in support of their quality improvement activities.

In the FY 2026 IPPS/LTCH PPS proposed rule, we included a request for information (RFI) on reducing the data submission deadline from 4.5 months to 45 days (90 FR 18353). We refer readers to the FY 2026 IPPS/LTCH PPS final rule (90 FR 37042) for a full summary of the public comments received.

#### (2) Proposal To Revise the LTCH QRP Assessment Data Submission Deadline

Beginning with the FY 2029 LTCH QRP, we are proposing that LTCHs must complete their data submissions and make corrections to their assessment data where necessary no later than the 15th day of the second month after the end of the calendar quarter. However, if the 15th day of the second month falls on a Friday, weekend, or Federal holiday, the date is delayed until 11:59 p.m. EST on the next business day. Specifically, we are proposing that LTCHs would follow the deadlines presented in Table IX.E.02 for the FY 2029 LTCH QRP. We also propose that similar calendar year data submission deadlines would apply to future years' payment determinations.

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**TABLE IX.E.-02 DATA COLLECTION TIMEFRAME AND DATA SUBMISSION DEADLINES FOR LCDS DATA AFFECTING THE FY 2029 PAYMENT DETERMINATION**

| Calendar Year (CY)<br>Quarter | Data Collection Timeframe   | Final Data Submission Deadlines for FY 2029<br>Payment Determination* |
|-------------------------------|-----------------------------|-----------------------------------------------------------------------|
| CY 2027 Quarter 1             | January 1–March 31, 2027    | May 17, 2027                                                          |
| CY 2027 Quarter 2             | April 1–June 30, 2027       | August 16, 2027                                                       |
| CY 2027 Quarter 3             | July 1–September 30, 2027   | November 15, 2027                                                     |
| CY 2027 Quarter 4             | October 1–December 31, 2027 | February 15, 2028                                                     |

\* Data submission deadlines will follow a similar quarterly schedule for subsequent CYs.

We believe that requiring LTCHs to submit LCDS assessment data by the 15th day of the second month after the end of the calendar quarter is reasonable. We conducted an analysis on the potential impact of reducing the timeframe by determining how many assessments are currently being submitted by this deadline, which is approximately within 45 days of the end of the quarter. Using 2024 data, we identified that 98.36 percent of all LCDS assessments were submitted to CMS within a 45-day timeframe. Of the remaining 1.64 percent submitted beyond 45 days, 0.08 percent were

submitted after the current 4.5-month data submission deadline and would not be further impacted by a change in the data submission deadline. Therefore, only 1.56 percent of LCDS assessments would be impacted by changing the data submission deadline from 4.5 months to require data submission by the 15th day of the second month after the end of the calendar quarter.

(3) Proposal To Revise the CDC NHSN Data Submission Deadlines

Beginning with the FY 2029 LTCH QRP, we are proposing that LTCHs must

complete their data submissions and make corrections to their CDC NHSN data where necessary no later than the 15th day of the second month after the end of the calendar quarter. However, if the 15th day of the second month falls on a Friday, weekend, or Federal holiday, the date is delayed until 11:59 p.m. EST on the next business day. Specifically, we are proposing that LTCHs would follow the deadlines presented in Table IX.E.03 for the FY 2029 LTCH QRP. We are also proposing that similar calendar year data submission deadlines would apply to future years' payment determinations.

**TABLE IX.E.-03 DATA COLLECTION TIMEFRAME AND DATA SUBMISSION DEADLINES FOR CDC NHSN LTCH QRP MEASURES AFFECTING THE FY 2029 PAYMENT DETERMINATION**

| Measure                                   | Data Collection Timeframe      | Final Data Submission Deadlines for FY 2029 Payment Determination* |
|-------------------------------------------|--------------------------------|--------------------------------------------------------------------|
| CAUTI                                     | January 1–March 31, 2027       | May 17, 2027                                                       |
| CLABSI                                    | April 1–June 30, 2027          | August 16, 2027                                                    |
|                                           | July 1–September 30, 2027      | November 15, 2027                                                  |
| CDI                                       | October 1–December 31, 2027    | February 15, 2028                                                  |
| COVID-19 Vaccination Coverage among HCP** |                                |                                                                    |
| Influenza Vaccination Coverage among HCP  | October 1, 2027–March 31, 2028 | May 15, 2028                                                       |

\* Data submission deadlines will follow a similar quarterly schedule for subsequent CYs.

\*\* In section IX.E.3 of the preamble of this proposed rule, we are proposing to remove this measure effective with the FY2028 LTCH QRP.

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We believe that requiring LTCHs to submit CDC NHSN assessment data by the 15th day of the second month after the end of the calendar quarter is reasonable. We note that there would be no change in the data submission deadline for the Influenza Vaccination Coverage among HCP measure, as the previously finalized data submission date is May 15th for each influenza season. We conducted an analysis on the potential impact of reducing the timeframe by determining how many LTCHs are currently reporting data by this deadline, which is approximately within 45 days of the end of the quarter. Using FY 2025 data, we identified that 88 percent of all LTCHs submitted CDC NHSN data within a 45-day timeframe.

On these bases, we believe revising the LTCH QRP data submission deadline for LCDS and CDC NHSN data to require LTCHs to submit CDC NHSN data by the 15th day of the second month after the end of the calendar quarter would improve the timeliness of public reporting by three months, which is beneficial to both consumers and LTCHs, with no change in burden to LTCHs.

We invite comment on this proposal to require LTCHs to submit LCDS assessment data and CDC NHSN data by the 15th day of the second month after the end of the calendar quarter beginning with the FY 2029 LTCH QRP.

**7. Policies Regarding Public Display of Measure Data for the LTCH QRP**

**a. Background**

For a more detailed discussion about our policies regarding public display of LTCH QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57231 through 57236).

**b. Proposal To End the Public Display of COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure**

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45438 through 45446), we finalized our proposal to publicly report the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP COVID-19 Vaccine) measure beginning with the September 2022 Care Compare refresh on Medicare.gov. In section

IX.E.3. of the preamble of this proposed rule, we are proposing to remove the HCP COVID-19 Vaccine) measure beginning with the FY 2028 LTCH QRP. If finalized as proposed, an LTCHs HCP COVID-19 measure data would be publicly reported for the last time with the September 2026 Care Compare refresh on Medicare.gov, based on data from Q4 of 2025. Thereafter, we would no longer display an LTCHs' HCP COVID-19 Vaccine measure data on the Care Compare tool at Medicare.gov.

We invite comment on our proposal to end public display of the HCP COVID-19 Vaccine measure data after the September 2026 Care Compare refresh on the Care Compare tool at Medicare.gov.

**c. Proposal To End the Public Display of the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure**

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59243 through 59250), we finalized our proposal to begin publicly displaying data for the Patient/Resident COVID-19 measure beginning with the September 2025 Care Compare refresh. In section IX.E.4. of the preamble of this proposed rule, we are proposing to

remove the Patient/Resident COVID–19 Measure beginning with the FY 2028 LTCH QRP. However, if this proposal is finalized, the reporting of data for the Patient’s COVID–19 vaccination is up to date data element would be voluntary effective October 1, 2026, through September 30, 2027. If finalized as proposed, we are proposing that the Patient/Resident COVID–19 Vaccine measure data would be publicly reported for the last time with the September 2026 Care Compare refresh on Medicare.gov, based on data from Q4 of 2025.

We invite public comment on our proposal to end the public display of Patient/Resident COVID–19 Vaccine measure data after the September 2026 Care Compare refresh on *Medicare.gov*.

#### *F. Proposed Changes to the Medicare Promoting Interoperability Program*

##### 1. Statutory Authority for the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs)

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act (as amended by the Health Information Technology for Economic and Clinical Health Act, Title XII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 [ARRA], Pub. L. 111–5) authorize downward payment adjustments under Medicare, beginning with FY 2015 for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for the applicable electronic health record (EHR) reporting periods. Section 602 of Title VI, Division O of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) added subsection (d) hospitals in Puerto Rico as eligible hospitals under the Medicare EHR Incentive Program (now known as the Medicare Promoting Interoperability Program) and extended

the participation timeline for these hospitals such that downward payment adjustments were authorized beginning in FY 2022 for section (d) Puerto Rico hospitals that do not successfully demonstrate meaningful use of CEHRT for the applicable EHR reporting periods.

##### 2. ONC Health IT Certification Program Proposed Updates Relevant to the Medicare Promoting Interoperability Program

###### a. Background

In the Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity proposed rule (90 FR 60970) (HTI–5 proposed rule), which appeared in the **Federal Register** on December 29, 2025, ONC<sup>421</sup> proposed a wide-ranging set of updates to the ONC Health IT Certification Program. The HTI–5 proposed rule focuses on deregulatory actions in 45 CFR part 170 (Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology) and 45 CFR part 171 (Information Blocking). The HTI–5 proposed rule seeks to reduce burden, offer flexibility to developers and providers, and support innovation through the removal and revision of certain certification criteria and regulatory provisions. The following summarizes proposals in the HTI–5 proposed rule that are relevant to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

In the HTI–5 proposed rule, ONC identified 34 certification criteria for

removal and 7 certification criteria for revision. ONC stated that removing or revising these criteria would reduce burden and costs for health IT developers and clinicians, partly due to the decreased necessity to maintain ongoing conformance with certification requirements (90 FR 60973).

We have summarized in Table IX.F.-01 the potential impact on Medicare Promoting Interoperability Program participants of the proposed certification criteria removals and revisions. Table IX.F.-01 describes how criteria that are the subject of HTI–5 proposals are incorporated into the definition of CEHRT in 42 CFR 495.4. In addition to the health IT certification criteria specified in the CEHRT definition in 42 CFR 495.4, the definition includes EHR technology certified under the ONC Health IT Certification Program that meets the Base EHR definition at 45 CFR 170.102 and technology certified to the criteria necessary to be a meaningful EHR user under the Medicare Promoting Interoperability Program. The criteria necessary to be a meaningful EHR user include criteria that are necessary to report on applicable objectives and measures under the Medicare Promoting Interoperability Program.

Several of the proposed changes in HTI–5 are described in further detail in associated proposals within this FY 2027 IPPS/LTCH PPS proposed rule. For more information, please see “Proposed Updates to the Definition of Certified Electronic Health Record Technology in the Medicare Promoting Interoperability Program” in section IX.F.2.b of this proposed rule and “Proposal to Remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information Measures” in section IX.F.4 of this proposed rule.

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<sup>421</sup> ASTP/ONC is now referred to as ONC, pursuant to a notice published in the **Federal Register** on April 1, 2026 (91 FR 16204). Although at the time of specific references noted herein ONC was either referenced as ASTP/ONC or as ONC, for clarity all references in this document are now noted as ONC.

**TABLE IX.F.-01. HTI-5 PROPOSED REMOVALS OR REVISIONS OF  
CERTIFICATION CRITERIA REFERENCED IN CEHRT DEFINITION FOR THE  
MEDICARE PROMOTING INTEROPERABILITY PROGRAM**

| <b>ONC Health IT Certification Criteria as defined in the following sections of Title 45 CFR 170.315</b> | <b>Remove/Revise</b> | <b>Timing</b>                       | <b>Relevance to the CEHRT Definition for the Medicare Promoting Interoperability Program</b>                                                                                                                                                             |
|----------------------------------------------------------------------------------------------------------|----------------------|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Patient Demographics and Observations - (a)(5)                                                           | Revise               | Effective date of HTI-5 final rule. | Specified in Base EHR definition.                                                                                                                                                                                                                        |
| Implantable Device List - (a)(14)                                                                        | Remove               | Effective date of HTI-5 final rule. | Specified in Base EHR definition.                                                                                                                                                                                                                        |
| Decision Support Interventions - (b)(11)                                                                 | Revise               | Effective date of HTI-5 final rule. | Specified in Base EHR definition.                                                                                                                                                                                                                        |
| Direct Project - (h)(1)                                                                                  | Remove               | Effective date of HTI-5 final rule. | Specified in Base EHR definition.                                                                                                                                                                                                                        |
| Direct Project, Edge Protocol, and XDR/XDM - (h)(2)                                                      | Remove               | Effective date of HTI-5 final rule. | Specified in Base EHR definition.                                                                                                                                                                                                                        |
| Family Health History - (a)(12)                                                                          | Remove               | Effective January 1, 2027.          | Specified in CEHRT definition.                                                                                                                                                                                                                           |
| Patient Health Information Capture - (e)(3)                                                              | Remove               | Effective January 1, 2027.          | Specified in CEHRT definition.                                                                                                                                                                                                                           |
| Automated Numerator Recording - (g)(1)                                                                   | Remove               | Effective January 1, 2027.          | Specified in CEHRT definition.                                                                                                                                                                                                                           |
| Automated Measure Calculation - (g)(2)                                                                   | Remove               | Effective January 1, 2027.          | Specified in CEHRT definition.                                                                                                                                                                                                                           |
| Transitions of Care - (b)(1)                                                                             | Revise               | Effective January 1, 2027.          | Specified criterion for the Support Electronic Referral Loops by Sending Health Information, Support Electronic Referral Loops by Receiving and Reconciling Health Information, HIE Bi-Directional Exchange, and Enabling Exchange Under TEFCA measures. |
| Clinical Information Reconciliation and Incorporation - (b)(2)                                           | Remove               | Effective January 1, 2027.          | Specified criterion for the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.                                                                                                                                   |
| View, Download, and Transmit to 3rd Party - (e)(1)                                                       | Revise               | Effective date of HTI-5 final rule. | Specified criterion for the Provide Patients Access measure.                                                                                                                                                                                             |
| Transmission to public health agencies Electronic Case Reporting - (f)(5)                                | Revise               | Effective date of HTI-5 final rule. | Specified criterion for the Electronic Case Reporting measure.                                                                                                                                                                                           |
| Transmission to public health agencies – Antimicrobial Use and Resistance Reporting - (f)(6)             | Revise               | Effective date of HTI-5 final rule. | Specified criterion for the Antimicrobial Use Surveillance and Antimicrobial Resistance Surveillance measures.                                                                                                                                           |
| Transmission to public health agencies – Health Care Surveys - (f)(7)                                    | Remove               | Effective January 1, 2027.          | Specified criterion for the Public Health Registry measure.                                                                                                                                                                                              |
| Application access — patient selection - (g)(7)                                                          | Remove               | Effective January 1, 2027.          | Specified criterion for the Provide Patients Access and HIE Bi-Directional Exchange measures.                                                                                                                                                            |
| Application Access – All Data Request - (g)(9)                                                           | Remove               | Effective January 1, 2027.          | Specified criterion for the Provide Patients Access and HIE Bi-Directional Exchange measures.                                                                                                                                                            |

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Proposed changes in the HTI-5 proposed rule would affect certification criteria referenced in the definition of CEHRT in 42 CFR 495.4 that applies to the Medicare Promoting Interoperability Program in several ways. First, several ONC proposals affect the ONC Health IT Certification Program certification criteria included within the Base EHR definition at 45 CFR 170.102, which is incorporated into the CEHRT definition at 42 CFR 495.4. Removal of these

criteria from the ONC Health IT Certification Program and the Base EHR definition would therefore remove the requirement that an eligible hospital or CAH must use CEHRT that includes this functionality. ONC proposed to remove from the Base EHR definition the certification criteria at: 45 CFR 170.315(a)(14)—“implantable device list” (90 FR 60983), 45 CFR 170.315(h)(1)—“transport methods and other protocols—direct project” (90 FR 60998), and 45 CFR 170.315(h)(2)—

“transport methods and other protocols—Direct Project, Edge Protocol, and XDR/XDM” (90 FR 60999). ONC also proposed to revise the following criteria referenced in the Base EHR definition: 45 CFR 170.315(a)(5)—“patient demographics and observations” (90 FR 60981 through 60982) and 45 CFR 170.315(b)(11)—“decision support interventions” (90 FR 60986 through 60987).

ONC also proposed to remove four certification criteria specified in the text

of the CEHRT definition at 42 CFR 495.4. ONC proposed to remove: 45 CFR 170.315(a)(12)—“family health history”, 45 CFR 170.315(e)(3)—“patient health information capture”, 45 CFR 170.315(g)(1)—“automated numerator recording”, and 45 CFR 170.315(g)(2)—“automated measure calculation” (90 FR 60982, 60991, 60994, and 60995). We further discuss these criteria in section IX.F.2.b of this proposed rule.

ONC also proposed to remove or revise other certification criteria that directly support certain Medicare Promoting Interoperability Program measures. For example, four certification criteria are identified as supporting the Provide Patients Electronic Access to Their Health Information measure: 45 CFR 170.315(e)(1), 45 CFR 170.315(g)(7), 45 CFR 170.315(g)(9), and 45 CFR 170.315(g)(10). Of these four criteria, three are impacted by the HTI–5 proposals. ONC proposed to revise 45 CFR 170.315(e)(1) (90 FR 60990 through 60991), and to remove 45 CFR 170.315(g)(7) and 45 CFR 170.315(g)(9) (90 FR 60998). If ONC finalizes these proposals, only the remaining criteria identified for the Provide Patients Electronic Access to Their Health Information measure (the revised 45 CFR 170.315(e)(1) and unaltered 45 CFR 170.315(g)(10)) would be necessary for eligible hospitals and CAHs to report the measure. The same would be true for all other measures for which removal or revision of applicable certification criteria are finalized in HTI–5. Table IX.F.–07, in section IX.F.8 of this proposed rule, contains a complete list of the Medicare Promoting Interoperability Program objectives and measures and their relevant ONC Health IT certification criteria, including the impact to individual certification criteria if HTI–5 proposals are finalized.

Regarding the Public Health Registry Reporting measure, ONC proposed to remove the only certification criterion (45 CFR 170.315(f)(7)—“transmission to public health agencies—health care surveys”) (90 FR 60994) that supports the measure. If the removal of the criterion is finalized, there will be no specific certification criteria identified for this measure. An eligible hospital or CAH would be able to use any available data exchange standard specified in 45 CFR part 170 subpart B to meet the measure. For example, the transmission could be in the form of a Consolidated Clinical Document Architecture (C–CDA) per 45 CFR 170.205(a)(4), or Quality Reporting Document Architecture (QRDA) per 45 CFR 170.205(h)(2).

Regarding the Electronic Case Reporting measure, ONC proposed to revise the criterion at 45 CFR 170.315(f)(5)—“transmission to public health agencies—electronic case reporting,” (90 FR 60992 through 60993) identified as supporting this measure. Regarding the Antimicrobial Use Surveillance and Antimicrobial Resistance Surveillance measures, ONC proposed to revise the criterion at 45 CFR 170.315(f)(6)—“transmission to public health agencies—antimicrobial use and resistance reporting,” (90 FR 60993) identified as supporting these measures. These proposals aim to update the certification criteria to focus on functional, rather than standards-based, requirements. While ONC’s proposed updates, if finalized, would revise the requirements for health IT products certified to these criteria, eligible hospitals and CAHs would continue to need to use health IT certified to these criteria to report the Electronic Case Reporting, Antimicrobial Use Surveillance, and Antimicrobial Resistance Surveillance measures.

We also note that ONC proposed removing certain certification criteria such as 45 CFR 170.315(g)(3)—“safety-enhanced design” and 45 CFR 170.315(g)(4)—“quality management system,” (90 FR 60995 through 60997) and a series of criteria related to privacy and security functionality in 45 CFR 170.315(d)(1)—(13) (90 FR 60989 through 60990), which are included in the Health IT Module certification requirements at 45 CFR 170.550. These criteria represent capabilities found in certified health IT products used by eligible hospitals and CAHs. We note that the proposed removal of these criteria from the ONC Health IT Certification Program would not affect an eligible hospital’s or CAH’s obligations to ensure the privacy and security of patients’ electronic health information under the Health Insurance Portability and Accountability Act of 1996 and other applicable laws.

Please see Table IX.F.–07. for a complete listing of ONC Health IT certification criteria that support each Medicare Promoting Interoperability Program measure, and which criteria ONC has proposed to remove or revise. In most cases, certification criteria that support measure reporting would remain part of the ONC Health IT Certification Program. For additional information regarding proposals in the HTI–5 proposed rule, please refer to the proposals at 90 FR 60970.

b. Proposed Updates to the Definition of Certified Electronic Health Record Technology in the Medicare Promoting Interoperability Program

For CY 2019 and subsequent years, the definition of CEHRT for the Medicare Promoting Interoperability Program at 42 CFR 495.4 requires the use of EHR technology certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to specified ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315. In paragraph (2)(i), the definition further specifies that EHR technology must be certified to criteria for “family health history” (45 CFR 170.315(a)(12)) and “patient health information capture” (45 CFR 170.315(e)(3)). In paragraph (2)(ii), the definition specifies that EHR technology must be certified to ONC health IT certification criteria that are necessary to be a meaningful EHR user. Paragraph (2)(ii)(A) includes the applicable measure calculation certification criteria at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

We are proposing to revise the definition of CEHRT at 42 CFR 495.4 for the Medicare Promoting Interoperability Program so the definition would be consistent with certain proposed modifications to ONC health IT certification criteria in the HTI–5 proposed rule. Specifically, we are proposing to remove references to the following certification criteria effective January 1, 2027:

- “family health history”—45 CFR 170.315(a)(12).
- “patient health information capture”—45 CFR 170.315(e)(3).
- “automated numerator recording”—45 CFR 170.315(g)(1).
- “automated measure calculation”—45 CFR 170.315(g)(2).

If finalized as proposed, effective January 1, 2027, these criteria would no longer be included in the CEHRT definition. The proposed revised definition in 42 CFR 495.4 would be, in relevant part, as follows:

“*Certified electronic health record technology (CEHRT)* [ . . . ]

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the



ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315—

(i) For 2019 through 2026, at 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) Necessary to be a Meaningful EHR User (as defined in this section), including the following:

(A) For 2019 through 2026, the applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) and can be electronically accepted by CMS.”

We note that while our proposal is consistent with the approach in the HTI–5 proposed rule (90 FR 60970), we do not believe that ONC must finalize its proposed revisions for us to finalize the changes proposed in this section for our regulatory definition of CEHRT for the Medicare Promoting Interoperability Program.

We believe that the longstanding presence of the criteria for “family health history” at 45 CFR 170.315(a)(12) and “patient health information capture” at 45 CFR 170.315(e)(3) in the ONC Health IT Certification Program and their incorporation into Medicare Promoting Interoperability Program requirements means that the functionality reflected in these criteria is fully embedded in certified health IT and is widely available and used by eligible hospitals and CAHs. ONC anticipates that health IT developers will continue to retain these capabilities in their Health IT Modules despite the absence of certification criteria for these functionalities (90 FR 60991 and 90 FR 60982). We note that these criteria are not identified as supporting any specific measures within the Medicare Promoting Interoperability Program.

Similarly, for the certification criteria needed for measure calculation (“automated numerator recording” and “automated measure calculation” certification criteria in 45 CFR 170.315(g)(1) and 45 CFR 170.315(g)(2)), health IT developers seeking to support customers participating in the Medicare Promoting Interoperability Program will need to continue to support reporting of numerators and denominators for certain Medicare Promoting Interoperability Program measures, including the Electronic Prescribing measure and Providing Patients Access

to Their Health Information measure. We believe removing the requirements for certification to 45 CFR 170.315(g)(1) and 45 CFR 170.315(g)(2), by removing references to those criteria in the definition of CEHRT in 42 CFR 495.4, will reduce administrative burden for health IT developers associated with testing and certifying to this functionality without impacting reporting requirements for the Medicare Promoting Interoperability Program.

In summary, we are proposing to revise the definition of CEHRT for the Medicare Promoting Interoperability Program at 42 CFR 495.4. Specifically, we are proposing to remove the certification criteria for “family health history” (45 CFR 170.315(a)(12)), “patient health information capture” (45 CFR 170.315(e)(3)), “automated numerator recording” (45 CFR 170.315(g)(1)), and “automated measure calculation” (45 CFR 170.315(g)(2)) effective January 1, 2027 in alignment with the proposed timing to remove such criteria from the Code of Federal Regulations in the HTI–5 proposed rule.

We invite public comment on these proposals.

### 3. Proposal To Remove ONC Direct Review and ONC–ACB Surveillance Attestations

#### a. Background

In the Medicare Program, Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models final rule with comment period, which appeared in the **Federal Register** on November 4, 2016 (hereafter the “CY 2017 Quality Payment Program final rule”) (81 FR 77027), we adopted two attestations for the Medicare Promoting Interoperability Program (then called the Medicare EHR Incentive Program) related to supporting providers with the performance of CEHRT. The two attestations, which are now found at 42 CFR 495.40(b)(2)(i)(I)(1) and (2), are:

- **ONC Direct Review attestation:** Eligible hospitals and CAHs must affirm cooperation with ONC Direct Review of their CEHRT by: (1) acknowledging the requirement to cooperate in good faith with ONC direct review of their health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received; and (2) if requested, cooperate in good faith with ONC direct review of their health information technology certified under the ONC Health IT Certification Program.<sup>422</sup>

<sup>422</sup> 42 CFR 495.40(b)(2)(i)(I)(1).

- **ONC–Authorized Certification Body (ONC–ACB) Surveillance attestation:** Eligible hospitals and CAHs may also attest that they engaged in supporting providers with the performance of CEHRT activities by attesting that they: (1) acknowledge the option to cooperate in good faith with ONC–ACB surveillance of their health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received; and (2) if requested, cooperated in good faith with ONC–ACB surveillance of their health information technology certified under the ONC Health IT Certification Program.<sup>423</sup>

The ONC Direct Review attestation is currently a required element of the Medicare Promoting Interoperability Program; submitting a “Yes” response, or claiming an applicable exclusion are the only means to fulfill the requirements of the attestation. The submission of a “No” response results in the eligible hospital or CAH failing to meet the attestation. Thus, the eligible hospital or CAH would consequently fail to meet minimum program requirements and not be considered a meaningful EHR user for the EHR reporting period, subjecting it to a downward payment adjustment. The ONC–ACB Surveillance attestation is optional: a “Yes” response on the attestation, a “No” response on the attestation, or non-response are all acceptable answers with respect to whether an eligible hospital or CAH is considered a meaningful EHR user for the EHR reporting period. Both attestations are reported through a manual attestation (“Yes” or “No”) process via the CMS Hospital Quality Reporting (HQR) system.

#### b. Proposal To Remove the ONC Direct Review and ONC–ACB Surveillance Attestations Beginning With the EHR Reporting Period in CY 2026

We are proposing to remove the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation from the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2026 and make conforming changes at 42 CFR 495.40(b)(2)(i)(I). These changes would be effective with the data submission period beginning January 1, 2027, because neither attestation requires any specific action to occur within the EHR reporting period. We believe this proposal advances our focus on high-value, outcome-oriented measures.

<sup>423</sup> 42 CFR 495.40(b)(2)(i)(I)(2).



While we continue to support ONC direct review and ONC-ACB surveillance, we also recognize the need to reduce administrative burdens in our measure and attestation set when feasible.

We continue to recognize the importance of ONC direct review and ONC-ACB surveillance activities and believe these mechanisms are important for mitigating issues with health IT products that may pose serious risks to public health or safety and continue to cooperate with ONC in supporting the ONC Health IT Certification Program. As stated in the CY 2017 Quality Payment Program final rule (81 FR 77020), efforts to strengthen surveillance and direct review of certified health IT are critical to the success of HHS programs and initiatives that require the use of certified health IT to improve health care quality and the efficient delivery of care. We do not anticipate that the commitment from ONC and the ONC-ACBs toward such goals will change.

When we initially finalized these attestations in November 2016 in the CY 2017 Quality Payment Program final rule, we believed that the attestations would complement and strengthen recent updates to ONC's ability to perform surveillance and direct review activities. Specifically in October 2015, ONC finalized the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications final rule, which added requirements that ONC-ACBs conduct more frequent and more rigorous surveillance of certified technology and capabilities "in the field" (80 FR 62707). Additionally in October 2016, ONC published the ONC Health IT Certification Program: Enhanced Oversight and Accountability final rule, which established regulatory processes to facilitate ONC's direct review and evaluation of the performance of certified health IT in certain circumstances (81 FR 72406). In the CY 2017 Quality Payment Program final rule, we determined that surveillance and direct review activities provided greater assurance to health care providers that their certified EHR technology would perform in a manner that meets their expectations, but that this surveillance and direct review would not be effective unless health care providers cooperated with these activities, including by granting access to and assisting ONC-ACBs and ONC to observe the performance of production systems (81 FR 77020).

While these activities remain important, we no longer believe that the requirement for eligible hospitals and CAHs to attest "yes" to the ONC Direct Review attestation is necessary to demonstrate the meaningful use of CEHRT. Since 2016, the ONC direct review process has become known to eligible hospitals and CAHs, and the value of participation has become evident without dependence on an annual attestation. Likewise, we believe ONC-ACB Surveillance attestation, which is optional for attestation, is no longer necessary to collect because eligible hospitals and CAHs have been made aware of their ability to participate in OCB-ACB surveillance if asked. We believe that the burden of the attestations, even the minimal burden of the voluntary ONC-ACB Surveillance attestation, now outweighs their value. This proposal aligns with our goals of reducing administrative burden while simultaneously focusing on high-value, outcome-oriented measures. Specifically, removal of these attestations from the Medicare Promoting Interoperability Program represents an opportunity to reduce the number of discrete manual steps and reporting fields required for successful program participation without diminishing the integrity or central goals of the program. Although we are proposing to remove the attestations, we strongly encourage eligible hospitals or CAHs to continue participating in these oversight processes when assistance is requested by ONC or an ONC-ACB.

We are proposing the removal of the ONC Direct Review and ONC-ACB Surveillance attestations beginning with the EHR reporting period in CY 2026 to reduce burden as quickly as feasible. Since eligible hospitals and CAHs would not be reporting on these attestations until the submission period that opens January 1, 2027, we have determined that it would be feasible for both hospitals and CMS to implement this change. Therefore, if this proposal is finalized, eligible hospitals and CAHs would not have to report on these attestations by the March 1, 2027, submission deadline and there would be no effect on their FY 2028 payment determination or FY 2026 cost reimbursement, respectively.

We invite public comment on this proposal.

#### 4. Proposal To Remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information Measures

##### a. Background on the Health Information Exchange Objective

The Health Information Exchange objective and its associated measures encourage and leverage the interoperability of electronic health information on a broader scale and promote health IT-based care coordination. The Health Information Exchange objective currently includes five measures: Support Electronic Referral Loops by Sending Health Information, Support Electronic Referral Loops by Receiving and Reconciling Health Information, HIE Bi-Directional Exchange, Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA), and Electronic Prior Authorization. For background on this objective and its associated measures, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41656 through 41661), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42596 through 42597), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58969), the FY 2022 IPPS/LTCH PPS final rule (86 FR 45465 through 45470), the FY 2023 IPPS/LTCH PPS final rule (87 FR 49327 through 49334), and the 2024 Interoperability and Prior Authorization final rule (89 FR 8926).

The Support Electronic Referral Loops by Sending Health Information measure requires, for at least one transition of care or referral, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care: (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

- *Numerator*: Number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.

- *Denominator*: Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (Place of Service [POS] 21 or 23) was the transitioning or referring provider.

The Support Electronic Referral Loops by Receiving and Reconciling Health Information measure requires, for at least one electronic summary of care record received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a

transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list using CEHRT.

- *Numerator*: The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient's known medication allergies; and (3) Current Problem List—Review of the patient's current and active diagnoses.

- *Denominator*: Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has not previously encountered the patient.

Under current policy (87 FR 49334), an eligible hospital or CAH must satisfy the Health Information Exchange objective by using one of three reporting options: Option 1 (report on the Support Electronic Referral Loops by Sending Health Information measure AND the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure), Option 2 (report on the HIE Bi-Directional Exchange measure), or Option 3 (report on the Enabling Exchange Under TEFCA measure). The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure are each worth 15 points within the Health Information Exchange objective, and an eligible hospital or CAH may receive up to a maximum of 30 points by reporting on both measures. Eligible hospitals and CAHs must also attest “Yes” on the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027 to meet all requirements for the Health Information Exchange objective (89 FR 8926 through 8927).<sup>424</sup>

We have identified two ONC health IT certification criteria in 45 CFR 170.315

as supporting Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure. In the “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017” final rule, we finalized that eligible hospitals and CAHs must use the “transitions of care” certification criterion at 45 CFR 170.315(b)(1) for the measure (80 FR 62882) that we subsequently renamed as the Support Electronic Referral Loops by Sending Health Information measure (83 FR 41658). In the FY 2019 IPPS/LTCH PPS final rule, for the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, we finalized that eligible hospitals and CAHs must utilize both the “transitions of care” certification criterion at 45 CFR 170.315(b)(1) and the “clinical information reconciliation and incorporation” certification criterion at 45 CFR 170.315(b)(2) (83 FR 41661). These certification criteria, based upon the C-CDA standard, enable eligible hospitals and CAHs to complete the actions described in the measures around sending, receiving, and reconciling summary of care records.

In the HTI-5 proposed rule (90 FR 60984 through 60985), ONC proposed multiple updates to the ONC Health IT Certification criteria that facilitate reporting the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures. Notably, ONC proposed to reduce the scope of the “transitions of care” certification criterion at 45 CFR 170.315(b)(1) to focus its requirements on enabling the receipt of a C-CDA document to position the criterion for a future evolution to receipt of Fast Healthcare Interoperability Resources® (FHIR®)-formatted data. ONC also proposed to remove the “clinical information reconciliation and incorporation” certification criterion at 45 CFR 170.315(b)(2) based on its review of industry adoption of the criterion. ONC's review found that the capabilities of the criterion are widely implemented and used in health IT and thus are not likely to go away as a supported capability by developers of certified health IT based solely on removal of the criterion from the ONC Health IT Certification Program. For more details regarding these ONC proposals in the HTI-5 proposed rule,

please see the HTI-5 proposed rule at 90 FR 60984.

b. Proposal To Remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information Measures Beginning With the EHR Reporting Period in CY 2028

We propose to remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2028. This proposal would streamline reporting and reduce the complexity of multiple measure reporting options for the Health Information Exchange objective, while focusing program performance on measures that assess the adoption of newer health information technologies and more comprehensive methods of information-sharing. If our proposal to remove these measures is finalized, beginning with the EHR reporting period in CY 2028, eligible hospitals and CAHs would fulfill requirements in the Health Information Exchange objective by attesting “Yes” to either the HIE Bi-Directional Exchange measure or the Enabling Exchange Under TEFCA measure, as well as attesting “Yes” or claiming an Exclusion on the Electronic Prior Authorization measure.<sup>425</sup>

The Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures have been present as measures of meaningful use since Stage 2 of the EHR Incentive Program, the precursor to the Medicare Promoting Interoperability Program (77 FR 54044). Since their initial adoption, these measures have supported widespread adoption of functionality in EHRs for supporting the exchange of summary care records using the C-CDA standard. Use of this functionality as advanced by the current measures and their predecessors has served as a key driver for the adoption and use of exchange capabilities across the health care landscape for over a decade.

With this baseline of functionality broadly available to eligible hospitals and CAHs, we began to explore additional measures that foster the availability of longitudinal care records for patients and facilitate enhanced care coordination across settings by adding

<sup>424</sup> In section IX.F.5 of this proposed rule, we are proposing several updates to the Electronic Prior Authorization measure.

<sup>425</sup> We have proposed modifications to the Electronic Prior Authorization measure in this proposed rule. For more information, please see section IX.F.5 of this proposed rule.

the Health Information Exchange (HIE) Bi-Directional Exchange measure and, later, the Enabling Exchange Under TEFCA measure (86 FR 45470 and 87 FR 49334, respectively). We are now seeking to further advance this work by removing the prior measures and transitioning eligible hospitals and CAHs to focus on broader-scale interoperability approaches by prioritizing pathways that leverage Health Information Exchanges and Qualified Health Information Networks (QHINs) under TEFCA.

This transition is consistent with trends already underway in the program. Since the HIE Bi-Directional Exchange and Enabling Exchange Under TEFCA measures were adopted in the program, we have seen increased reporting of these measures to meet the Health Information Exchange objective. For the EHR reporting period in CY 2024, which is the most recent program data available, 68.8 percent of reporting eligible hospitals and CAHs reported on the HIE Bi-Directional Exchange measure and 4.6 percent of reporting facilities reported on the Enabling Exchange Under TEFCA measure, while only 26.6 percent of reporting eligible hospitals and CAHs reported on the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures. CAHs are disproportionately represented among the facilities that report the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures, with 33.1% of CAHs compared to 23.9% of eligible hospitals reporting the measures. However, this statistic also shows that a majority of both eligible hospitals and CAHs have been able to successfully report either the HIE Bi-Directional Exchange measure or the Enabling Exchange Under TEFCA measure. We believe that these measures of participation in network-based exchange are more comprehensive indicators of meaningful health information exchange than the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures. For example, exchanging information through an HIE or entity participating in TEFCA supports on-demand patient health information exchange to any location in an entire network of participants rather than the submission of a summary of care document to a single specified

recipient. We therefore believe that removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures, although impacting the eligible hospitals and CAHs that report on those measures, benefits patients by assessing regional and national network-based longitudinal health information exchange among these eligible hospitals and CAHs rather than assessing the transmission of patient information to a single location at a single point in time. We also believe that all eligible hospitals, including small, rural hospitals, and CAHs benefit from increased access to patient health information for the patients they treat through increased participation in health information exchanges or TEFCA. Removal of these measures would also streamline reporting and reduce program complexity by decreasing the overall number of measures in the program. We welcome comments with respect to whether there are additional barriers beyond what we have mentioned that small hospitals, rural hospitals, or CAHs may encounter to successfully report either the HIE Bi-Directional Exchange measure or Enabling Exchange Under TEFCA measure.

Finally, we also believe that removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures, which are C-CDA-based measures, will encourage eligible hospitals and CAHs to further explore new exchange modalities that move away from document-centric standards and point-to-point exchange. The current Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures focus on the exchange of summary of care records using the C-CDA standard, but industry trends toward increased FHIR adoption have enabled easier scalability to support real-time data exchange and access to more discrete data elements when compared to the document-centric CDA standard.<sup>426</sup> We seek to improve the use of electronic health records over time, and one such aspect of doing so is fostering eligible hospitals' and CAHs' use of emerging data exchange

standards that may improve upon those that were adopted in prior years.

We note that our proposal to remove these measures does not imply that the underlying exchange activities targeted by the Health Information Exchange objective are fully and effectively implemented at this time, including among eligible hospitals and CAHs. We are considering evaluating performance-based measures under the Health Information Exchange objective for future rulemaking. Specifically, we plan to continue to evaluate future potential changes to the current HIE Bi-Directional Exchange and Enabling Exchange Under TEFCA measures to transition from attestation-based to performance-based measures to drive further improvement around ongoing gaps in health information exchange among eligible hospitals and CAHs. We also note that we expect the use of C-CDA based exchange to continue to serve as an ongoing capability for health information exchange even though we have determined that the Medicare Promoting Interoperability Program no longer needs a measure of its adoption and use. While our proposal to remove these measures from the Medicare Promoting Interoperability Program seeks to encourage the use of new technology approaches that improve the function of electronic health records over time, we acknowledge the impact and value of these exchange methods.

We propose removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2028, rather than in an earlier reporting period, to provide the 26.6 percent of eligible hospitals and CAHs currently reporting on these measures sufficient time to prepare for reporting on the HIE Bi-Directional Exchange measure or the Enabling Exchange Under TEFCA measure. Making these proposals effective in the EHR reporting period in CY 2028 would allow those eligible hospitals and CAHs time to plan, procure, configure, and validate new workflows for participation with an entity facilitating health information exchange, whether through the HIE Bi-Directional Exchange or the Enabling Exchange Under TEFCA measures. This additional lead time would support a safe and reliable transition, while eligible hospitals and CAHs that wish to transition earlier and report on HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA, if they are not already doing so, will be able to do so for the EHR reporting period in CY 2026

<sup>426</sup> <https://healthit.gov/data/data-briefs/hospital-use-of-apis-to-enable-data-sharing-between-ehrs-and-third-party-technology/>.

or CY 2027 if they so choose. Although eligible hospitals and CAHs may incur additional costs as a result of joining a Health Information Exchange or a QHIN under TEFCa to report either of the measures respectively, we believe that these benefits outweigh the costs considering the value of broad health information exchange networks to patient care<sup>427</sup> and the fact that such networks are more valuable to each participant as more and more participants are present in the network.<sup>428</sup>

Following the removal of these measures, we propose that eligible hospitals and CAHs would be required to satisfy the Health Information Exchange objective by reporting the HIE Bi-Directional Exchange measure or reporting the Enabling Exchange Under TEFCa measure. We propose to maintain the same scoring policy for these two measure options; attesting “Yes” to either the HIE Bi-Directional Exchange or Enabling Exchange Under TEFCa measure would result in a maximum score of 30 points. Additionally, eligible hospitals would be required to meet the Electronic Prior Authorization measure requirement in the Health Information Exchange objective, which we discuss in section IX.F.5 of this rule.

We invite public comment on these proposals.

## 5. Proposed Updates to the Electronic Prior Authorization Measure

### a. Background

In the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we adopted the Electronic Prior Authorization measure under the Health Information Exchange objective in the Medicare Promoting Interoperability Program. We finalized that eligible hospitals and CAHs would be required to attest to the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027 (89 FR 8910). For purposes of the Electronic Prior Authorization measure, a prior authorization request must be made using a Prior Authorization Application Programming Interface (API) using data from CEHRT to attest “Yes” to the measure, unless the eligible hospital or CAH claims an applicable

exclusion. We finalized the following text for the measure description (89 FR 8916):

*For at least one hospital discharge and medical item or service (excluding drugs) ordered during the EHR reporting period, the prior authorization is requested electronically via a Prior Authorization API using data from CEHRT.*

• *Exclusions: Any eligible hospital or CAH that—*

++ *Does not order any medical items or services (excluding drugs) requiring prior authorization during the EHR reporting period.*

++ *Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets CMS’s specified Prior Authorization API requirements during the applicable EHR reporting period.*

Only a “Yes” attestation, or claiming an applicable exclusion, fulfills the requirements of the measure. Additionally, we finalized that the measure will not be scored (that is, not assigned points for a “Yes” attestation) for the EHR reporting period in CY 2027. A “No” attestation will result in the eligible hospital or CAH not meeting the measure. The eligible hospital or CAH would therefore not meet minimum program requirements and not be considered a meaningful EHR user for the relevant EHR reporting period and be subject to a downward payment adjustment (89 FR 8911).

The 2024 CMS Interoperability and Prior Authorization final rule also finalized that Medicare Advantage plans, state Medicaid Fee-for-service (FFS) programs, state Children’s Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plans (QHP) issuers on the federally facilitated exchanges (collectively referred to as “impacted payers”) must implement and maintain a Prior Authorization API beginning in CY 2027 (by January 1, 2027 for MA organizations and state Medicaid and CHIP FFS programs; by the first rating period beginning on or after January 1, 2027 for Medicaid managed care plans and CHIP managed care entities; and for plan years beginning on or after January 1, 2027 for individual market QHP issuers on the FFEs) (89 FR 8759 through 8760). In that rule we also recommended, rather than required, specific FHIR Implementation Guides (IGs) to support the APIs (89 FR 8937).

In the Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule

(HTI–4 final rule), which was published as part of the FY 2026 IPPS/LTCH PPS final rule (90 FR 37164 through 37182), ONC finalized three ONC health IT certification criteria for electronic prior authorization, based on the following FHIR IGs:

- “Provider prior authorization API—coverage requirements discovery” in 45 CFR 170.315(g)(31);
- “Provider prior authorization API—documentation templates and rules” in 45 CFR 170.315(g)(32); and
- “Provider prior authorization API—prior authorization support” in 45 CFR 170.315(g)(33).

These certification criteria are based on three IGs developed by the HL7 Da Vinci project, which ONC adopted in the HTI–4 final rule<sup>429</sup> at 45 CFR 170.215(j)(1), (2), and (3):

- HL7® FHIR® Da Vinci—Coverage Requirements Discovery (CRD) IG;
- HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) IG; and
- HL7 FHIR Da Vinci—Prior Authorization Support (PAS) IG.

Together, these certification criteria can enable multiple prior authorization workflows for healthcare providers. We refer readers to the HTI–4 final rule (90 FR 37162 through 37175) for a more detailed discussion of ONC’s finalized certification criteria at 45 CFR 170.315(g)(31) through (33) and section XI.B.4.b (90 FR 36541 through 36542) of the same rule for a summary of all the finalized ONC policies.

We also recently released the “Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges” proposed rule (2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule). Among other policies, in the 2026 CMS Interoperability and Prior Authorization for Drugs proposed rule, we proposed to require impacted payers to implement and maintain Prior Authorization APIs that conform to the CRD, DTR, and PAS IGs adopted by ONC on behalf of the Secretary at 45 CFR 170.215(j)(1), (2), and (3). We proposed that compliance dates for impacted payers to conform to

<sup>427</sup> Menachemi N, Rahurkar S, Harle CA, Vest JR. The benefits of health information exchange: an updated systematic review. *Journal of the American Medical Informatics Association*. 2018 Sep;25(9):1259–65.

<sup>428</sup> Yaraghi N, Du AY, Sharman R, Gopal RD, Ramesh R. Network effects in health information exchange growth. *ACM Transactions on Management Information Systems (TMIS)*. 2013 Apr 1;4(1):1–26.

<sup>429</sup> In the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, ONC has proposed updated versions of these implementation guides.

the proposed standards and IGs would begin October 1, 2027 (however, impacted payers must still implement Prior Authorization APIs beginning in CY 2027). Finally, in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, ONC proposed to adopt updated versions of the CRD, DTR, and PAS IGs. If finalized, these proposed updated versions would enable payers to implement Prior Authorization APIs and health IT developers implementing the finalized health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) to utilize the latest versions of these specifications.

The proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule for impacted payers to implement and maintain the Prior Authorization APIs using the CRD, DTR, and PAS IGs, along with the provisions ONC finalized in the HTI-4 final rule to adopt the CRD, DTR, and PAS IGs and establish electronic prior authorization certification criteria for health IT developers, collectively support the Electronic Prior Authorization measure for eligible hospitals and CAHs and advance interoperability applying consistent standards across HHS programs. For more information, please see the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule and the HTI-4 final rule for the three health IT certification criteria to support electronic prior authorization at 45 CFR 170.315(g)(31), (32), and (33) finalized by ONC in the HTI-4 final rule (90 FR 37169).

**b. Proposal To Modify the Electronic Prior Authorization Measure Beginning With the EHR Reporting Period in CY 2027**

We propose making several changes to the Electronic Prior Authorization Measure, reflected in the following modified text for the measure description:

*For at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT.*

In this proposed measure update, we have revised the phrase “using data from CEHRT” to read “using CEHRT” because in section IX.F.5.c of this proposed rule we clarify the requirement to use health IT certified to specific certification criteria included in the definition of CEHRT for this measure. When we adopted the Electronic Prior Authorization measure,

we did not identify specific ONC health IT certification criteria required to complete the actions specified in the measure (89 FR 8910 through 8915). We stated that gathering structured data from CEHRT would be achievable without additional certification criteria specific to the measure (89 FR 8925), which had not been proposed or finalized at the time of the 2024 CMS Interoperability and Prior Authorization final rule. The proposed update to the measure language to state that a prior authorization must be requested electronically “using CEHRT” is consistent with the availability of certified Health IT Modules that must be used to complete the action specified in the Electronic Prior Authorization measure.

We also propose to change the word “discharge” to “encounter” to more clearly delineate that a prior authorization request may occur at any time during the hospital encounter, rather than be associated temporally with the discharge, about which some stakeholders had expressed confusion regarding the measure. At this time, we are not proposing to modify the exclusion criteria finalized when we adopted the Electronic Prior Authorization measure (89 FR 8916).

We invite public comment on this proposal.

We also considered proposing to revise the measure to include a broader set of actions associated with the prior authorization process. Specifically, we considered whether to propose to revise the measure language so that an eligible hospital or CAH would be able to attest to the measure by using CEHRT to conduct a check for whether an item or service requires prior authorization, regardless of whether the query results in a request and approval of the prior authorization. We request comment on whether the added flexibility associated with such an alternative approach would make a meaningful difference for eligible hospitals and CAHs, especially those seeking to initially focus on adoption of the functionality in the “provider prior authorization API—coverage requirements discovery” criterion.

We also considered whether to include prior authorization for drugs administered during the hospitalization in the measure at this time. These actions could be supported by technology certified to the certification criteria in 45 CFR 170.315(g)(31), (32), and (33). We request comment on whether adding drugs to the measure would be of benefit.

**c. Health IT Certification Criteria To Support the Electronic Prior Authorization Measure**

In light of our proposal that an electronic prior authorization must be requested using CEHRT to satisfy the Electronic Prior Authorization measure, and the finalization of health IT certification criteria in 45 CFR 170.315(g)(31), (32), and (33) in the HTI-4 final rule, we are specifying the use of health IT certified to these certification criteria as required for the Electronic Prior Authorization measure. Use of certified health IT to support electronic prior authorization transactions included in the measure would ensure that eligible hospitals and CAHs have standards-based capabilities within their health IT systems to interact with Prior Authorization APIs established by impacted payers and successfully complete the measure.

As discussed above, the three certification criteria are based on the HL7 Da Vinci CRD, DTR, and PAS IGs, and address different parts of the electronic prior authorization workflow. The “provider prior authorization API—coverage requirements discovery” in 45 CFR 170.315(g)(31) enables a health care provider to request information from payers about coverage requirements. Where further information is needed to support a prior authorization request, the “provider prior authorization API—documentation templates and rules” criterion in 45 CFR 170.315(g)(32) provides a mechanism for clinicians and other EHR users to navigate and quickly assemble the information needed to support a prior authorization request according to a payer’s requirements. Finally, the “provider prior authorization API—prior authorization support” in 45 CFR 170.315(g)(33) enables submission of prior authorization requests from health IT systems as well as checking the status of a previously submitted request. By finalizing each component of the workflow as a separate certification criterion, ONC sought to support a more dynamic health IT marketplace in which a health IT developer could develop Health IT Modules demonstrating conformance to all three IGs or focus on a specific element or elements (90 FR 37169).

Different prior authorization scenarios that allow an eligible hospital or CAH to successfully attest to the Electronic Prior Authorization measure may require the functionality of one, or more than one, Health IT Modules certified to the criteria in 45 CFR 170.315(g)(31), (32), and (33). For instance, an eligible hospital or CAH could successfully

report on the measure using CEHRT that only includes a Health IT Module certified to the “provider prior authorization API—coverage requirements discovery” criterion in 45 CFR 170.315(g)(31). Consider a hypothetical scenario in which a Medicare Advantage (MA) enrollee has stable coronary artery disease and new exertional dyspnea (feeling shortness of breath during physical exertion). The beneficiary’s cardiologist, working in an eligible hospital or CAH, wants to order an outpatient transthoracic echocardiogram (TTE) to assess left ventricular function and valvular disease. When the cardiologist places an order for a TTE in the EHR, a Health IT Module certified to the “provider prior authorization API—coverage requirements discovery” criterion (45 CFR 170.315(g)(31)) automatically sends a real-time query to the beneficiary’s MA plan endpoint to determine whether prior authorization is required for the requested service (the TTE) and, if so, what documentation is needed. The MA plan returns a CRD response (via CDS Hooks “card”<sup>430</sup>) indicating that prior authorization is necessary and has been approved under the beneficiary’s plan benefits and network status, including information such as the prior authorization number and assumed billing codes.

In this hypothetical scenario, the prior authorization request is satisfied using only the capabilities represented with the “provider prior authorization API—coverage requirements discovery” certification criterion (45 CFR 170.315(g)(31)). The health care provider submitted a query for prior authorization, the payer responded that prior authorization was required, the prior authorization was approved, and the health care provider received a response indicating this approval from the payer using the payer’s API. In this case, the receipt of an approval indicates that the health care provider effectively submitted a request for prior authorization, consistent with the requirements of the Electronic Prior Authorization measure.

However, in other scenarios, the initial prior authorization query from a health care provider to a payer could result in a response indicating the need for additional information before a determination as to whether prior authorization is approved or denied can be provided, based on the coverage requirements identified. Additional

certified Health IT Modules supporting additional elements of the electronic prior authorization workflow would then need to be used to submit the prior authorization request after collecting the necessary documentation.

Consider another hypothetical scenario where an MA enrollee has been diagnosed with metastatic colorectal cancer. The beneficiary’s oncologist, working in an eligible hospital or CAH, has ordered a PET–CT scan and immunotherapy infusion. In this scenario, the oncologist places the order for a PET–CT scan and immunotherapy infusion in the EHR, which is certified to the “provider prior authorization API—coverage requirements discovery” criterion (45 CFR 170.315(g)(31)) and automatically queries the beneficiary’s MA plan’s FHIR API. The EHR receives a response via CDS Hooks card indicating that prior authorization is required for both services and describes coverage criteria and documentation needs. Because the EHR is also certified to 45 CFR 170.315(g)(32), the certified health IT enables the oncologist to complete prior authorization following the DTR IG. An embedded SMART on FHIR app fetches the payer’s specific documentation template and rules for oncology prior authorizations. For the PET–CT, the payer’s documentation rules ask for the cancer staging information and previous imaging results; for immunotherapy, the payer’s documentation rules require the patient’s biomarker (for example, PD–L1 expression) status, prior treatment history, and recent lab results. Much of this information can be auto populated because the embedded DTR app uses Clinical Quality Language (CQL) logic and FHIR queries to pull the beneficiary’s latest CT scan report and lab results from their medical record, and it confirms her cancer diagnosis and stage from the problem list. The oncologist answers a few additional questions (such as confirming the beneficiary has no contraindications and that a required biomarker test was positive) within the embedded DTR app. By the end of this step, the EHR has compiled all necessary supporting documentation for the prior authorization, ensuring the request will be complete.

Next, the oncologist’s office submits the prior authorization request electronically using the capabilities under the “provider prior authorization API—prior authorization support” criterion (45 CFR 170.315(g)(33)) to bundle the request and documentation and send it to the MA plan’s prior authorization endpoint. This bundle is transmitted via a FHIR RESTful

interaction to the payer, as defined by the PAS IG. The EHR’s certified Health IT Module ensures the request conforms to the required FHIR structure and sends it securely. Because all required information was provided up front and matched the plan’s coverage criteria, the MA plan’s system could potentially automatically adjudicate and approve the requests in near real-time. If that happened, the oncologist could now schedule the beneficiary’s therapy without delay, confident that the services are covered.

Both scenarios described result in a prior authorization request that successfully satisfies the action required by the proposed Electronic Prior Authorization measure and therefore would allow the eligible hospital or CAH to successfully report the measure. However, each example utilized different combinations of Health IT Modules certified to electronic prior authorization certification criteria in 45 CFR 170.315(g)(31), (32), and (33). In the first scenario, the health care provider used a Health IT Module certified to the “provider prior authorization API—coverage requirements discovery” criterion (45 CFR 170.315(g)(31)) to complete actions necessary for the eligible hospital or CAH successfully attest “Yes” to the measure. In the second scenario, the health care provider used Health IT Modules certified to all three of the electronic prior authorization certification criteria to complete all actions for the eligible hospital or CAH to successfully attest “Yes” to the measure.

Consistent with these hypothetical examples, we note that an eligible hospital or CAH would be able to successfully attest to the measure using only those certified Health IT Modules necessary for the eligible hospital or CAH to complete the measure. Eligible hospitals and CAHs would not be required to adopt additional electronic prior authorization certified Health IT Modules if they are not needed for the purposes of successfully reporting the measure. We expect that the ability to utilize different combinations of certified Health IT Modules to meet the measure will afford eligible hospitals, CAHs, and health IT developers flexibility in how they deploy, adopt, and use different aspects of certified health IT functionality for electronic prior authorization.

d. Proposal To Make the Electronic Prior Authorization Measure a Bonus Measure for the EHR Reporting Period in CY 2027

We are proposing to modify our previously finalized requirement that an

<sup>430</sup> A CDS Hooks card is a user-facing, real-time alert or suggestion returned by a Clinical Decision Support (CDS) service to an EHR in response to a specific clinical event. See <https://cds-hooks.org/> for additional information.

eligible hospital or CAH must report the Electronic Prior Authorization measure to be considered a meaningful EHR user for the EHR reporting period in CY 2027 (89 FR 8911). For multiple reasons, we believe that eligible hospitals and CAHs may need additional time and flexibility before requiring the Electronic Prior Authorization measure. First, we recognize that eligible hospitals, CAHs, and health IT developers will need additional time for procurement, integration, and testing to operationalize standards-based electronic prior authorization capabilities that support the Electronic Prior Authorization measure. Second, stakeholders have indicated that achieving widespread implementation and routine use of these capabilities in CY 2027 may be challenging, particularly for small, rural, and otherwise under-resourced eligible hospitals and CAHs. Third, we expect additional implementation complexity for eligible hospitals, CAHs, and their vendors due to proposed changes in Prior Authorization API standards requirements that would occur in CY 2027. For these reasons, we believe that a year of optional reporting will both incentivize adoption of CEHRT through bonus points and offer flexibility to those hospitals and CAHs that could benefit from additional time to test, implement, and deploy CEHRT functionality necessary to support electronic prior authorization.

Therefore, we are proposing to make the Electronic Prior Authorization measure, with the proposed measure updates, optional and eligible for 10 bonus points for eligible hospitals and CAHs that attest “Yes” to the measure for the EHR reporting period in CY 2027. Allocating 10 bonus points is an appropriate and effective incentive to promote the adoption and use of certified technology for requesting electronic prior authorizations among eligible hospitals and CAHs. Should we finalize this proposal to make the measure optional, an eligible hospital or CAH attesting “No” will not earn any bonus points, but attesting “No” will also not result in the eligible hospital or CAH failing to meet the measure, and, therefore, failing to meet minimum program requirements and not being considered a meaningful EHR user for the EHR reporting period in CY 2027. This would be a modification to the policy we adopted for this measure in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8911). Optional reporting for the first year is particularly important for small, rural, or otherwise under-resourced eligible hospitals and CAHs navigating new

measure requirements while minimizing and balancing burden.

Should we finalize this proposal, exclusions would not be available for the Electronic Prior Authorization measure for the EHR reporting period in CY 2027, as exclusions are unnecessary for optional measures. Only those eligible hospitals and CAHs that attest “Yes” to the measure would receive the 10 bonus points. Given the time eligible hospitals and CAHs have had to become familiar with the Electronic Prior Authorization measure since the 2024 Interoperability and Prior Authorization final rule, we believe proposing this as an optional bonus measure solely for the EHR reporting period in CY 2027 would provide eligible hospitals and CAHs enough time to adopt and begin utilizing the certified health IT necessary to successfully report the Electronic Prior Authorization measure. We invite public comment on these proposals.

#### e. Proposal To Require the Electronic Prior Authorization Measure Beginning With the EHR Reporting Period in CY 2028

When we adopted the Electronic Prior Authorization measure in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we finalized that eligible hospitals and CAHs would be required to attest to the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027 (89 FR 8910) and that only a “Yes” attestation, or claiming an applicable exclusion, would fulfill the requirements of the measure. Additionally, we finalized that although the measure would not be scored (that is, not assigned points for a “Yes” attestation) for the EHR reporting period in CY 2027, a “No” attestation would result in the eligible hospital or CAH not meeting the measure. The eligible hospital or CAH would therefore not meet minimum program requirements and not be considered a meaningful EHR user for the relevant EHR reporting period and be subject to a downward payment adjustment (89 FR 8911).

As discussed in section IX.F.5.d, we are proposing to make the Electronic Prior Authorization measure optional for the EHR reporting period in CY 2027. Should we finalize the proposal to make the measure an optional bonus measure for the EHR reporting period in CY 2027, we are also proposing that eligible hospitals and CAHs would be required to attest “Yes” to the updated Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2028. Consistent with the revised text we have proposed for the

measure, we are proposing that an eligible hospital or CAH must request a prior authorization electronically using CEHRT to send a request through a payer’s Prior Authorization API for at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period to attest “Yes” to the measure, or else the eligible hospital or CAH must claim an applicable exclusion. Only a “Yes” attestation or claiming an applicable exclusion would fulfill the requirements of the measure. A “No” response would result in the eligible hospital or CAH not meeting measure requirements. And if an eligible hospital or CAH does not meet the measure requirements, it would not meet minimum program requirements nor be considered a meaningful EHR user for an EHR reporting period, and therefore, the hospital would be subject to a downward payment adjustment. This proposal mirrors the response requirements we adopted when we first adopted the measure but proposes to apply them to the EHR reporting period in CY 2028. We are proposing this modification to provide eligible hospitals and CAHs and additional time to prepare to successfully report the measure, consistent with our proposal to make the measure an optional bonus measure for the EHR reporting period in CY 2027.

The measure exclusions originally adopted in the 2024 Interoperability and Prior Authorization final rule (89 FR 8916 through 8923) would be available to eligible hospitals and CAHs for the EHR reporting period in CY 2028 and subsequent years. The available exclusions would be: (1) an eligible hospital or CAH did not order any medical item or services (excluding drugs) requiring prior authorization during the EHR reporting period; or (2) the eligible hospital or CAH only ordered medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets CMS’s specified Prior Authorization API requirements during the applicable EHR reporting period.

When we adopted the Electronic Prior Authorization measure in the 2024 Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we finalized that eligible hospitals and CAHs would report the measure as an unscored attestation for only the EHR reporting period in CY 2027 (89 FR 8910), but we did not specify its scoring methodology for subsequent years because we determined that it would be more appropriate to determine the



measure's scoring structure closer in time to its effective date. In this proposed rule, we are also proposing that the Electronic Prior Authorization measure would remain unscored for the EHR reporting period in CY 2028 and subsequent years, which would allow time for eligible hospitals and CAHs to adjust to the new electronic prior authorization workflow using Prior Authorization APIs without undue focus on scoring implications in the Medicare Promoting Interoperability Program. We believe that the Electronic Prior Authorization measure will retain its importance as an aspect of health information exchange.

We invite public comment on this proposal.

#### f. Request for Information on Future Potential Performance-Based Measure of Electronic Prior Authorization

While we believe the current measure requirement of achieving "at least one" electronic prior authorization is appropriate for the initial inclusion of the measure in the Medicare Promoting Interoperability Program, we do not expect this minimal requirement to effectively increase electronic prior authorization usage over time. Therefore, we are seeking comments on potential future updates we could make to this measure to incentivize providers to use electronic prior authorization for a more substantial set of the electronic prior authorization requests that they submit over the course of an EHR reporting period. Consistent with statutory requirements in section 1886(n)(3)(A)(ii) of the Act, we envision that expanding the scope of the measure in future rulemaking would lead to increased interoperable exchange of data that would not only decrease administrative burden, but could improve the quality of health by reducing the time needed for a patient to get access to necessary medical services and items. Reducing delays in the exchange of data and as a result providing patients care more efficiently, drives better care coordination, which is a key objective of meaningful use. Additionally, because electronic prior authorization requires data sharing, this advances interoperability, which is a primary focus of meaningful use.

We also intend to drive consistent adoption of certified health IT capabilities supporting the complete electronic prior authorization workflow over time, by requiring eligible hospitals and CAHs to address a wider array of prior authorization requests that require more complex interactions with payers. The public input we receive will contribute to future considerations for

potentially updating the Electronic Prior Authorization measure in a manner that helps achieve HHS's goals of promoting meaningful use of certified EHR technology, electronic exchange of health information, and submission of clinical quality measures.

We invite comments on how we can further strengthen the Electronic Prior Authorization measure in a manner that incentivizes progress while minimizing burden on eligible hospitals and CAHs. We also seek comment on barriers and challenges small, rural, or otherwise under-resourced eligible hospitals and CAHs might face reporting a performance-based electronic prior authorization measure.

#### 6. Proposal To Adopt a Unique Device Identifiers for Implantable Medical Devices Measure in the Public Health and Clinical Data Exchange Objective

##### a. Background

Under section 519(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(f)), the Food and Drug Administration (FDA) issued regulations establishing a unique device identification system<sup>431</sup> for medical devices (78 FR 58786).<sup>432</sup> The Unique Device Identifier (UDI) is a standard identifier that adequately identifies a medical device from manufacturing through distribution to patient use. The UDI is composed of the Device Identifier (UDI-DI), which identifies the version or model of a device, and the Production Identifier(s) (UDI-PI), which contain production information about a device such as lot or batch number, serial number, expiration and manufacturing dates, and distinct identification code for human cellular or tissue-based products.<sup>433</sup> The FDA UDI system requires device labelers to include UDIs on device labels and packages in both human readable form and machine-readable form such that it can be read by a bar code scanner or other similar technology,<sup>434</sup> and submit device identification information to FDA's Global Unique Device Identification Database (GUDID), which is accessible from two public portals, AccessGUDID<sup>435</sup> and OpenFDA.<sup>436</sup>

<sup>431</sup> For more information, see: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

<sup>432</sup> <https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system>.

<sup>433</sup> <https://accessgudid.nlm.nih.gov/about-gudid#what-is-udi>.

<sup>434</sup> <https://www.fda.gov/media/99084/download>.

<sup>435</sup> <https://accessgudid.nlm.nih.gov/>.

<sup>436</sup> <https://open.fda.gov/apis/device/udi/>.

FDA designed the UDI system to serve multiple public health objectives by enabling rapid and accurate device identification throughout distribution and use (78 FR 58786). UDIs can reduce medical errors by allowing healthcare providers to positively identify devices and access key attributes through GUDID rather than consulting multiple and potentially inconsistent sources, thus eliminating confusion that can lead to inappropriate device use. The UDI system also allows for accurate identification of devices associated with adverse events, enabling manufacturers and FDA to more rapidly aggregate and analyze related reports, isolate underlying problems, and develop appropriate solutions for safety issues. Routine inclusion of UDIs as discrete data elements in EHRs and registries would enable accurate identification of devices used during patient care delivery, facilitate rapid notification and follow-up care during recalls, and improve care coordination across providers. Additionally, discrete documentation of UDI strengthens real world data sources for use across the device lifecycle. This would improve FDA's ability to conduct post-market surveillance and outcomes-based research.<sup>437</sup> UDIs also enable more efficient and effective inventory and supply chain management, providing the foundation for a global, secure distribution chain, helping to address counterfeiting and diversion while supporting preparedness for medical emergencies.

While the foundation for the UDI system is established with UDI present on device labels and data available in GUDID, the healthcare system has yet to achieve broad adoption of UDI documentation. Fully realizing the benefits of the UDI system depends on UDIs being integrated into data sources throughout the healthcare system, including the supply chain, EHRs, medical device registries, and claims.<sup>438</sup> Multiple barriers and challenges to UDI adoption have been noted,<sup>439</sup> including lack of knowledge across the health care system about the benefits and return on investment for

<sup>437</sup> <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>.

<sup>438</sup> Wang X, Ayakulangara Panickan V, Cai T, Xiong X, Cho K, Cai T, Bourgeois FT. Endovascular aneurysm repair devices as a use case for postmarketing surveillance of medical devices. *JAMA Internal Medicine*. 2023 Oct;183(10):1090–7.

<sup>439</sup> Rathi VK, Ross JS, Redberg RF. Unique device identifiers—missing in action. *JAMA internal medicine*. 2023 Oct;183(10):1049–50.

<sup>440</sup> [https://nestcc.org/wp-content/uploads/NESTcc-UDI-Playbook\\_11-15-2022.pdf](https://nestcc.org/wp-content/uploads/NESTcc-UDI-Playbook_11-15-2022.pdf).



UDI implementation, and lack of regulatory and policy mandates.

However, capabilities to capture UDI in health IT systems have been widely adopted by eligible hospitals and CAHs. In the ONC Health IT Certification Program, the “implantable device list” certification criterion at 45 CFR 170.315(a)(14) requires Health IT Modules certified to the criterion to record and allow a user to access a list of UDIs associated with a patient’s implantable devices. This certification criterion is currently included in the Base EHR definition and has been widely implemented in health IT products, with 341 Health IT Modules identified as certified to the criterion. Other certification criteria also support the use of UDI. Under the “standardized API for patient and population services” criterion in 45 CFR 170.315(g)(10), which is also included in the Base EHR definition, a certified Health IT Module must be able to make UDI information for a patient’s implantable device(s) available using a standards-based API according to the HL7® FHIR® US Core Implementation Guide STU 6.1.0 FHIR Implementation Guide. Additionally, the criteria at 45 CFR 170.315(b)(1)—“transitions of care” and 45 CFR 170.315(b)(2)—“clinical information reconciliation and incorporation,” which have long been required for measures in the Health Information Exchange Objective, support the ability for providers to receive, send, and reconcile documents that contain UDI information.

Wide use of products certified to these criteria by eligible hospitals and CAHs indicates that eligible hospitals and CAHs have the ability to store and exchange UDIs if they document them.<sup>441</sup> Published evidence via health system case studies show that capturing UDI via barcode scanning at the point of care is operationally feasible.<sup>442 443</sup> In cardiac catheterization lab implementation studies, barcode scanning was successfully integrated into routine workflow to link device identifiers to clinical records.<sup>444</sup> Frontline nursing evaluations in surgical services report that implant barcode scanning is workable in practice.<sup>445</sup> Together, these studies

demonstrate that structured UDI captured in EHRs using barcode technology can be implemented without substantial workflow disruption.

#### b. Proposal To Adopt Unique Device Identifiers for Implantable Devices Measure Beginning With the EHR Reporting Period in CY 2027

The routine, electronic capture and discrete storage of UDIs for implantable medical devices directly advances the Secretary’s core responsibility, articulated in the statutory authority for the Medicare Promoting Interoperability Program, to improve the use of electronic health records and health care quality over time. Such electronic capture and discrete storage of UDIs would advance the safety of health care, an essential element of health care quality. Broader use of UDIs is similarly aligned with the meaningful use of CEHRT through the Medicare Promoting Interoperability Program. A primary aspect of the meaningful use of CEHRT is whether valuable data are captured at the point of care and available for subsequent exchange and use by health care providers. For example, in the “Medicare and Medicaid Programs; Electronic Health Record Incentive Program” final rule (75 FR 44328), we implemented, in the precursor program to the Medicare Promoting Interoperability Program, multiple data capture-related measures such as “Record Smoking Status” and “Maintain Active Medication List” because, as we noted, the availability of pertinent clinical data is important to the meaningful use of CEHRT. Integrating a UDI-focused measure into the Program would foster consistent workflows for capturing device data as discrete EHR elements and strengthen the ability of eligible hospitals, CAHs, beneficiaries, and public health agencies to use interoperable health information to improve outcomes, manage risk, and respond rapidly to device-related safety concerns. Multiple studies and pilots have discussed the ease of UDI capture at the point of care through bar code scanning, storage in the EHR, and transmission to the health plan through claims.<sup>446 447</sup>

services. CIN: Computers, Informatics, Nursing. 2020 Mar 1;38(3):131–8.

<sup>446</sup> Krupka, Dan C. Ph.D., et al. Transmitting Device Identifiers of Implants From the Point of Care to Insurers: A Demonstration Project. *Journal of Patient Safety* 17(3):p 223–230, April 2021. | DOI: 10.1097/PTS.0000000000000828 *Journal of Patient Safety*.

<sup>447</sup> N Wilson, et al., Advancing Patient Safety Surrounding Medical Devices: Barriers, Strategies, and Next Steps in Health System Implementation of Unique Device Identifiers—PubMed.

Therefore, we are proposing to adopt the following Unique Device Identifiers for Implantable Medical Devices measure under the Public Health and Clinical Data Exchange objective. We believe this measure will additionally further public health surveillance benefits that would arise from capturing the UDI for implantable medical devices.

**Measure Description:** The eligible hospital or CAH uses CEHRT during the EHR reporting period to electronically capture and store, as one or more discrete data elements within the patient’s electronic health record, the complete Unique Device Identifier (UDI), which includes the device identifier and, when present on the device label, the production identifier, for each implantable medical device subject to UDI requirements used for patient care delivery.

**Reporting Requirements:** “Yes” or “No” attestation.

**Exclusion:** The eligible hospital or CAH implanted five or fewer medical devices subject to UDI requirements during the calendar year of the applicable EHR reporting period.

We are proposing to require eligible hospitals and CAHs to attest to this measure beginning with the EHR reporting period in CY 2027. For this measure, eligible hospitals and CAHs would be required to attest “Yes” or “No” to meet measure requirements or claim an applicable exclusion. Not providing a “yes” or “no” attestation would result in failure to meet minimum program requirements, and the eligible hospital or CAH would be subject to a downward payment adjustment. No points will be assigned to this measure; rather, it would be one of seven measures required to satisfy the Public Health and Clinical Data Exchange objective. We are proposing to allow both “Yes” and “No” responses to fulfill measure requirements as part of our proposal to initially adopt the measure, which would allow eligible hospitals and CAHs to become familiar with the concept of UDI and highlight its importance while avoiding undue burden. We also note that we specify in the proposed measure that it only applies to implantable medical devices subject to UDI requirements under 21 CFR 801.20(a) and 21 CFR part 830, subpart E, which represents most implantable medical devices. However, some devices, such as investigational devices, devices for research use only, and custom devices, are exempt from UDI requirements and would therefore also be exempt from this measure. We highlight here that we intend to propose modifying the measure in future rulemaking to further promote the

<sup>441</sup> <https://chpl.healthit.gov/#/search>.

<sup>442</sup> <https://www.ahrmm.org/resource-repository-ahrmm/stanford-health-care-udi-capture-work-group-case-study-2017-1>.

<sup>443</sup> <https://www.ahrmm.org/resource-repository-ahrmm/baptist-health-udi-capture-work-group-case-study-2017-1>.

<sup>444</sup> <https://pubmed.ncbi.nlm.nih.gov/27343161/>.

<sup>445</sup> Wilson N, Jehn M, Kisana H, Reimer D, Meister D, Valentine K, Reiser M, Clarke H. Nurses’ perceptions of implant barcode scanning in surgical

appropriate capture of UDIs within the EHR. We are proposing one exclusion for the UDIs for Implantable Medical Devices Measure. We invite comments on any additional exclusions that should be considered for this measure.

As discussed, there are numerous health IT certification criteria that reference UDI, including the “implantable device list” certification criterion in 45 CFR 170.315(a)(14) which would be required to support the measure. However, we note that ONC proposed to remove this criterion in the HTI-5 proposed rule (90 FR 60983), and if ONC finalizes removal of this criterion we would not reference this criterion as required to support the measure. Separate from this dedicated certification criterion, the UDI is a named data element within the US Core Data for Interoperability Version 3 as the “Unique Device Identifier(s) for a patient’s implantable device(s)”<sup>448</sup> and therefore is a supported element within the HL7® FHIR® US Core Implementation Guide STU 6.1.0 FHIR Implementation Guide,<sup>449</sup> which Health IT Modules certified to the certification criterion at 45 CFR 170.315(g)(10) must be capable of using to respond to requests for patient data. We are also identifying the criterion at 45 CFR 170.315(g)(10) as required to support fulfillment of the measure, which is also part of the Base EHR definition in 45 CFR 170.102 and thus already incorporated into the definition of CEHRT at 42 CFR 495.4. We welcome comments as to whether other certification criteria should be considered to support this measure.

We invite public comment on these proposals. We also invite comments on the feasibility of the timeline and any additional exclusions that we should consider for this measure in future rulemaking.

#### c. Request for Information on the Future Direction of the Proposed Unique Device Identifiers for Implantable Devices Measure and Additional Options for Utilizing UDI

Should we adopt the measure, we would also intend to consider future modifications to this measure and invite public comment on the following questions.

##### Performance-Based Measure

- How could we design a feasible performance-based measure (for example, with a numerator and

denominator) to assess the meaningful use of UDI data? How should the denominator be defined (for example, all implantable devices used during patient care delivery, specific procedure codes, specific device categories)? Are there specific data sources or definitions that would be appropriate and less burdensome for identifying the denominator population?

- Are there categories of implantable devices for which UDI capture would be particularly challenging for a performance-based measure? If so, please describe the specific challenges.

• What performance measure can we utilize to ensure the data quality of the UDI captured during patient care delivery is valid and usable? Should we require that the CEHRT validate UDI accuracy and format against the GUDID?

- When multiple implantable medical devices are used on a given patient during a given care episode, would there be any challenges in complete documentation of all device UDIs for a performance-based measure? If so, please describe the specific challenges.

• Should we consider adopting a future measure that assesses whether the eligible hospital or CAH makes UDI data available for exchange via certified health IT, for example, using the standardized FHIR API for patient and population services?

- Should we require in a measure that an eligible hospital or CAH must record UDIs for relevant devices in patient discharge summaries, after-visit summaries, or in patient portals?

• What measures could we adopt to show that a health care provider working in an eligible hospital or CAH uses the UDI to compare quality among devices, track recalls, and coordinate patient follow-up care including across health systems and for revision surgery or explanation?

- Should CMS consider introducing a performance threshold for any such measure with a numerator and denominator? Should CMS consider phased-in implementation with increasing thresholds over time for a performance-based measure?

##### Additional UDI Options

- Are there other CMS programs or care settings (for example, hospital outpatient, ambulatory surgery centers, nursing homes, skilled nursing facilities, rehabilitation centers or office-based practices) through which we should consider addressing appropriate UDI capture and exchange? What would be the most appropriate means to do so?

• What technical barriers, if any, exist that would prevent other care settings or non-hospital provider types from

capturing UDIs at the point of care (for example, barcode scanning infrastructure, EHR system limitations, integration with surgical and supply chain systems)?

- Are there existing workflows or technologies that could reduce burden regarding better utilization of UDI data exchange while maintaining data quality (for example, automated scanning at point of use, integration with supply chain systems)?

Comments received in response to this RFI may inform future rulemaking.

#### 7. Overview of Scoring Methodology

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636), we adopted a performance-based scoring methodology for eligible hospitals and CAHs reporting to the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019. This methodology included a minimum scoring threshold that eligible hospitals and CAHs must meet in addition to the requirement to report on the objectives and measures of meaningful use under 42 CFR 495.24. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), we finalized a proposal to increase the performance-based scoring threshold to 70 points for the EHR reporting period in CY 2025 and to 80 points beginning with the EHR reporting period in CY 2026.

As shown in Table IX.F.–02., as proposed for the EHR reporting period in CY 2027, the points associated with the required measures sum to 100 points, and reporting on one or more of the optional bonus measures (including the Electronic Prior Authorization measure should we finalize our proposal for that to be a bonus measure for CY 2027), offers up to an additional 15 bonus points. The scores for each of the required measures and bonus measures are added together to calculate a total score of up to 115 possible points for each eligible hospital or CAH. We refer readers to Table IX.F.–02. in this proposed rule, which reflects the objectives, measures, maximum points available, and whether a measure is required or optional for the EHR reporting period in CY 2027 based on our previously adopted policies and the proposals included in this proposed rule.

As shown in Table IX.F.–03., as proposed for the EHR reporting period in CY 2028 and subsequent years, the points associated with the required measures still sum to 100 points, although the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health

<sup>448</sup> For more information, see: <https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi#uscdi-v3>.

<sup>449</sup> For more information, see: <https://hl7.org/fhir/us/core/STU6.1/>.

|                                                                                                                                                                                                                           |                                                                                                                                                                                                                      |                                                                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| Information would no longer be an option to report for the Health Information Exchange objective based on proposals in this proposed rule. The Electronic Prior Authorization measure is proposed to return as a required | measure beginning with the EHR reporting period in CY 2028, and 5 bonus points remain available under the Public Health and Clinical Data Exchange objective. The scores for each of the required measures and bonus | measures are added together to calculate a total score of up to 105 possible points for each eligible hospital or CAH.<br><b>BILLING CODE 4120-01-P</b> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|

**TABLE IX.F.-02.: PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY  
FOR EHR REPORTING PERIOD IN CY 2027**

| Objective                                | Measure                                                                                                                                                                                                                                                                                                                                                                                  | Maximum Points             | Required/Optional                                                                     |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|---------------------------------------------------------------------------------------|
| Electronic Prescribing (e-Prescribing)   | e-Prescribing                                                                                                                                                                                                                                                                                                                                                                            | 10 points                  | Required                                                                              |
|                                          | Query of Prescription Drug Monitoring Program (PDMP)                                                                                                                                                                                                                                                                                                                                     | 10 points                  | Required                                                                              |
| Health Information Exchange              | Support Electronic Referral Loops by Sending Health Information<br>-AND-                                                                                                                                                                                                                                                                                                                 | 15 points                  | Required (eligible hospitals and CAHs must choose one of the three reporting options) |
|                                          | Support Electronic Referral Loops by Receiving and Reconciling Health Information<br>-OR-                                                                                                                                                                                                                                                                                                | 15 points                  |                                                                                       |
|                                          | HIE Bi-Directional Exchange<br>-OR-                                                                                                                                                                                                                                                                                                                                                      | 30 points                  |                                                                                       |
|                                          | Enabling Exchange Under TEFCA                                                                                                                                                                                                                                                                                                                                                            | 30 points                  |                                                                                       |
|                                          | Electronic Prior Authorization*                                                                                                                                                                                                                                                                                                                                                          | 10 points ( <i>bonus</i> ) |                                                                                       |
|                                          |                                                                                                                                                                                                                                                                                                                                                                                          |                            |                                                                                       |
|                                          |                                                                                                                                                                                                                                                                                                                                                                                          |                            |                                                                                       |
| Provider to Patient Exchange             | Provide Patients Electronic Access to Their Health Information                                                                                                                                                                                                                                                                                                                           | 25 points                  | Required                                                                              |
| Public Health and Clinical Data Exchange | Report the following seven measures:<br><ul style="list-style-type: none"> <li>• Syndromic Surveillance Reporting</li> <li>• Immunization Registry Reporting</li> <li>• Electronic Case Reporting</li> <li>• Electronic Laboratory Reporting</li> <li>• Antimicrobial Use Surveillance</li> <li>• Antimicrobial Resistance Surveillance</li> <li>• Unique Device Identifier**</li> </ul> | 25 points                  | Required                                                                              |
|                                          | Report one of the following measures:<br><ul style="list-style-type: none"> <li>• Public Health Registry Reporting</li> <li>• Clinical Data Registry Reporting</li> <li>• Public Health Reporting with TEFCA</li> </ul>                                                                                                                                                                  | 5 points ( <i>bonus</i> )  | Optional                                                                              |

Notes: The Security Risk Analysis measure, SAFER Guides measure, and Information Blocking attestation required by section 106(b)(2)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 are required but will not be scored. Reporting electronic clinical quality measures (eQMs) is required but will not be scored. Eligible hospitals and CAHs must also submit their level of active engagement for measures under the Public Health and Clinical Data Exchange objective. Participants may spend only one EHR reporting period at Option 1: Pre-production and Validation level per measure and must progress to Option 2: Validated Data Production level for the following EHR reporting period. See the FY 2023 IPPS/LTCII PPS final rule (87 FR 49337) for more details about active engagement. In section IX.F.3 of this proposed rule, we are proposing to remove the ONC Direct Review and ONC-ACB Surveillance attestations for the EHR reporting period in CY 2026 and subsequent years.

\* In section IX.F.5.d of this proposed rule, we are proposing that the Electronic Prior Authorization measure be an optional bonus measure for CY 2027 EHR reporting period.

\*\* In section IX.F.6 of this proposed rule, we are proposing to adopt the Unique Device Identifier measure beginning with the EHR reporting period in CY 2027.

**TABLE IX.F.-03. : PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY  
FOR EHR REPORTING PERIOD IN CY 2028 AND SUBSEQUENT YEARS**

| Objective                                | Measure                                                                                                                                                                                                                                                                                                                                                                                   | Maximum Points            | Required/Optional                                                                   |
|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-------------------------------------------------------------------------------------|
| Electronic Prescribing (e-Prescribing)   | e-Prescribing                                                                                                                                                                                                                                                                                                                                                                             | 10 points                 | Required                                                                            |
|                                          | Query of Prescription Drug Monitoring Program (PDMP)                                                                                                                                                                                                                                                                                                                                      | 10 points                 | Required                                                                            |
| Health Information Exchange*             | HIE Bi-Directional Exchange                                                                                                                                                                                                                                                                                                                                                               | 30 points                 | Required (eligible hospitals and CAHs must choose one of the two reporting options) |
|                                          | -OR-                                                                                                                                                                                                                                                                                                                                                                                      |                           |                                                                                     |
|                                          | Enabling Exchange Under TEFCA                                                                                                                                                                                                                                                                                                                                                             | 30 points                 | Required                                                                            |
|                                          | Electronic Prior Authorization**                                                                                                                                                                                                                                                                                                                                                          | Unscored                  |                                                                                     |
| Provider to Patient Exchange             | Provide Patients Electronic Access to Their Health Information                                                                                                                                                                                                                                                                                                                            | 25 points                 | Required                                                                            |
| Public Health and Clinical Data Exchange | Report the following seven measures:<br><ul style="list-style-type: none"> <li>• Syndromic Surveillance Reporting</li> <li>• Immunization Registry Reporting</li> <li>• Electronic Case Reporting</li> <li>• Electronic Laboratory Reporting</li> <li>• Antimicrobial Use Surveillance</li> <li>• Antimicrobial Resistance Surveillance</li> <li>• Unique Device Identifier***</li> </ul> | 25 points                 | Required                                                                            |
|                                          | Report one of the following measures:<br><ul style="list-style-type: none"> <li>• Public Health Registry Reporting</li> <li>• Clinical Data Registry Reporting</li> <li>• Public Health Reporting with TEFCA</li> </ul>                                                                                                                                                                   | 5 points ( <i>bonus</i> ) | Optional                                                                            |

Notes: The Security Risk Analysis measure, SAFER Guides measure, and Information Blocking attestation required by section 106(b)(2)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 are required but will not be scored. Reporting electronic clinical quality measures (eCQMs) is required but will not be scored. Eligible hospitals and CAHs must also submit their level of active engagement for measures under the Public Health and Clinical Data Exchange objective. Participants may spend only one EHR reporting period at Option 1: Pre-production and Validation level per measure and must progress to Option 2: Validated Data Production level for the following EHR reporting period. See the FY 2023 IPPS/LTCH PPS final rule (87 FR 49337) for more details about active engagement. In section IX.F.3 of this proposed rule, we are proposing to remove the ONC Direct Review and ONC-ACB Surveillance attestations for the EHR reporting period in CY 2026 and subsequent years.

\*In section IX.F.4 of this proposed rule, the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures are proposed to be removed for the EHR reporting period in CY 2028 and subsequent years.

\*\* In section IX.F.5 of this proposed rule, we are proposing to make the Electronic Prior Authorization optional in the CY 2027 EHR reporting period and required, but unscored, starting EHR reporting period in CY 2028.

\*\*\* In section IX.F.6 of this proposed rule, we are proposing to adopt the Unique Device Identifier measure beginning with the EHR reporting period in CY 2027.

The maximum number of points available for each measure described in Tables IX.F.-02. and IX.F.-03. do not include the points that would be redistributed in the event an exclusion is claimed for a given measure. We are not proposing any changes to our policy for point redistribution in the event an exclusion is claimed. We refer readers to

Tables IX.F.-04. in this proposed rule, which shows point redistribution among the objectives and measures for the EHR reporting period in CY 2027 in the event an eligible hospital or CAH claims an exclusion. Similarly, Table IX.F.-05. shows the redistribution for the EHR reporting periods in CY 2028 and subsequent years.

We note that we adopted and codified a measure suppression policy for the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2026 at § 495.24(f)(3) in the Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B

Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program final rule (CY 2026 PFS final rule) (90 FR 49881). Specifically, we codified that if certain circumstances occur that impact our assessment of the

performance of eligible hospitals and CAHs on a measure selected for the Medicare Promoting Interoperability Program, we have the sole discretion to suppress the affected measure by excluding it from our assessment of performance. In this case, we would allocate the maximum points available

or provide full credit for the affected measure if the eligible hospital or CAH reports the affected measure, or we would exclude the affected measure from the determination of a meaningful EHR user if the affected measure is not scored. For more information, see the CY 2026 PFS final rule at 90 FR 49881.

**TABLE IX.F.-04. : EXCLUSION REDISTRIBUTION FOR THE EHR REPORTING PERIOD IN CY 2027**

| Objective                                | Measure                                                                                                                                                                                                                                                                                                                                           | Redistribution if Exclusion is Claimed                                                                                                                               |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e-Prescribing                            | e-Prescribing                                                                                                                                                                                                                                                                                                                                     | 10 points to Health Information Exchange objective                                                                                                                   |
|                                          | Query of PDMP                                                                                                                                                                                                                                                                                                                                     | 10 points to e-Prescribing measure                                                                                                                                   |
| Health Information Exchange              | Support Electronic Referral Loops by Sending Health Information*                                                                                                                                                                                                                                                                                  | No exclusion                                                                                                                                                         |
|                                          | -AND-                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                      |
|                                          | Support Electronic Referral Loops by Receiving and Reconciling Health Information*                                                                                                                                                                                                                                                                | No exclusion                                                                                                                                                         |
|                                          | -OR-                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                      |
|                                          | HITE Bi-Directional Exchange                                                                                                                                                                                                                                                                                                                      | No exclusion                                                                                                                                                         |
|                                          | -OR-                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                      |
|                                          | Enabling Exchange Under TEFCA                                                                                                                                                                                                                                                                                                                     | No exclusion                                                                                                                                                         |
| Provider to Patient Exchange             | Electronic Prior Authorization (Optional)                                                                                                                                                                                                                                                                                                         | No exclusion                                                                                                                                                         |
|                                          | Provide Patients Electronic Access to Their Health Information                                                                                                                                                                                                                                                                                    | No exclusion                                                                                                                                                         |
| Public Health and Clinical Data Exchange | Report the following seven measures: <ul style="list-style-type: none"> <li>• Syndromic Surveillance Reporting</li> <li>• Immunization Registry Reporting</li> <li>• Electronic Case Reporting</li> <li>• Electronic Laboratory Reporting</li> <li>• AU Surveillance</li> <li>• AR Surveillance</li> <li>• Unique Device Identifier***</li> </ul> | If an exclusion is claimed for each of the seven measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure |

\* In section IX.F.4 of this proposed rule, we propose to remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2028 and for subsequent years.

\*\* In section IX.F.5 of this proposed rule, we are proposing to make the Electronic Prior Authorization optional in the CY 2027 EHR reporting period

\*\*\* In section IX.F.6 of this proposed rule, we are proposing to adopt the Unique Device Identifier measure beginning with the EHR reporting period in CY 2027.

**TABLE IX.F.-05. : EXCLUSION REDISTRIBUTION FOR THE EHR REPORTING PERIOD IN CY 2028 AND SUBSEQUENT YEARS**

| Objective                                | Measure                                                                                                                                                                                                                                                                                                                                           | Redistribution if Exclusion is Claimed                                                                                                                               |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e-Prescribing                            | e-Prescribing                                                                                                                                                                                                                                                                                                                                     | 10 points to Health Information Exchange objective                                                                                                                   |
|                                          | Query of PDMP                                                                                                                                                                                                                                                                                                                                     | 10 points to e-Prescribing measure                                                                                                                                   |
| Health Information Exchange*             | HIE Bi-Directional Exchange                                                                                                                                                                                                                                                                                                                       | No exclusion                                                                                                                                                         |
|                                          | -OR-                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                      |
|                                          | Enabling Exchange Under TEFCA                                                                                                                                                                                                                                                                                                                     | No exclusion                                                                                                                                                         |
|                                          | Electronic Prior Authorization**                                                                                                                                                                                                                                                                                                                  | No exclusion                                                                                                                                                         |
| Provider to Patient Exchange             | Provide Patients Electronic Access to Their Health Information                                                                                                                                                                                                                                                                                    | No exclusion                                                                                                                                                         |
| Public Health and Clinical Data Exchange | Report the following seven measures: <ul style="list-style-type: none"> <li>• Syndromic Surveillance Reporting</li> <li>• Immunization Registry Reporting</li> <li>• Electronic Case Reporting</li> <li>• Electronic Laboratory Reporting</li> <li>• AU Surveillance</li> <li>• AR Surveillance</li> <li>• Unique Device Identifier***</li> </ul> | If an exclusion is claimed for each of the seven measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure |

\* In section IX.F.4 of this proposed rule, the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures are proposed to be removed for the EHR reporting period in CY 2028 and subsequent years.

\*\* In section IX.F.5 of this proposed rule, we are proposing to make the Electronic Prior Authorization required but unscored starting with the EHR reporting period in CY 2028.

\*\*\* In section IX.F.6 of this proposed rule, we are proposing to adopt the Unique Device Identifier measure beginning with the EHR reporting period in CY 2027.

#### 8. Overview of Objectives and Measures

Table IX.F.-06. lists objectives and measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2027 and reflects the proposals in this proposed rule as

well as proposed changes that would go into effect for the EHR reporting period beginning with CY 2028. For measures that have differing information between the EHR reporting period in CY 2027 and the EHR reporting period in CY

2028 and subsequent years, then the applicable year will be noted in the measure column. Table IX.F.-07. lists the ONC health IT certification criteria required to meet specific objectives and measures.

**TABLE IX.F.-06. : PROPOSED OBJECTIVES AND MEASURES FOR THE  
MEDICARE PROMOTING INTEROPERABILITY PROGRAM FOR THE EHR  
REPORTING PERIODS IN CY 2027, CY 2028 AND SUBSEQUENT YEARS**

| <b>Objective</b>            | <b>Measure</b>                                                                                                                                                                                                                                                                                                                | <b>Numerator</b>                                                                         | <b>Denominator</b>                                                                                                                                                                                        | <b>Exclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Calculation considerations related to counting unique patients or actions</b>                                                                                                                                                       |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e-Prescribing               | e-Prescribing:<br><br>For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are transmitted electronically using CEHRT.                                                                                                                                    | The number of prescriptions in the denominator generated and transmitted electronically. | The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed, other than controlled substances for patients discharged during the EHR reporting period. | Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions, and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.                                                                                                                                                                                                                        | Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data. |
| e-Prescribing               | Query of PDMP:<br><br>For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses CEHRT to conduct a query of a PDMP for prescription drug history.                                                               | N/A (measure is Y/N)                                                                     | N/A (measure is Y/N)                                                                                                                                                                                      | (1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include Schedule II, III and IV drugs and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period.<br>(2) Any eligible hospital or CAH that could not report on this measure in accordance with applicable law. | N/A (measure is Y/N)                                                                                                                                                                                                                   |
| Health Information Exchange | Electronic Prior Authorization (EHR Reporting Period in CY 2027 only):*<br><br>For at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT. | N/A (measure is Y/N)                                                                     | N/A (measure is Y/N)                                                                                                                                                                                      | None*                                                                                                                                                                                                                                                                                                                                                                                                                                                              | N/A (measure is Y/N)                                                                                                                                                                                                                   |



|                             |                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                       |                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                          |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Health Information Exchange | <p>Electronic Prior Authorization (EHR Reporting Period in CY 2028 and Subsequent Year):**</p> <p>For at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT.</p>                                                        | N/A (measure is Y/N)                                                                                                                                  | N/A (measure is Y/N)                                                                                                                                                                                                                  | Any eligible hospital or CAH that: (1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the EHR reporting period; or (2) Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets the Prior Authorization API requirements during the applicable EHR reporting period.* | N/A (measure is Y/N)                                                                                                                                                                                                                     |
| Health Information Exchange | <p>Support Electronic Referral Loops by Sending Health Information: (EHR Reporting Period in CY 2027 only)**</p> <p>For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) Electronically exchanges the summary of care record.</p> | Number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.** | Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (Place of Service [POS] 21 or 23) was the transitioning or referring provider.** | None**                                                                                                                                                                                                                                                                                                                                                                                                     | Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.** |

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                   |        |                                                                                                                                                                                                                                                 |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Health Information Exchange | <p>Support Electronic Referral Loops by Receiving and Reconciling Health Information (EHR Reporting Period in CY 2027 <i>only</i>):**</p> <p>For at least one electronic summary of care record received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list using CEHRT.</p> | <p>Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient’s medication, including the name, dosage, frequency, and route of each medication; (2) Medication Allergy – Review of the patient’s known medication allergies; and (3) Current Problem List – Review of the patient’s current and active diagnoses.**</p> | <p>Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.**</p> | None** | <p>Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.**</p> |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|------|----------------------|
| Health Information Exchange | <p>HIE Bi-Directional Exchange</p> <p>The eligible hospital or CAH must attest to the following:</p> <p>(1) Participating in a Health Information Exchange system (HIE) in order to enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.</p> <p>(2) Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.</p> <p>(3) Using the functions of CEHRT to support bi-directional exchange with an HIE.</p> | N/A (measure is Y/N) | N/A (measure is Y/N) | None | N/A (measure is Y/N) |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|------|----------------------|

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                      |                      |      |                      |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|------|----------------------|
| Health Information Exchange | <p>Enabling Exchange Under TEFCA</p> <p>The eligible hospital or CAH must attest to the following:</p> <p>(1) Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the <b>Federal Register</b> and on ONC's website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.</p> <p>(2) Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.</p> | N/A (measure is Y/N) | N/A (measure is Y/N) | None | N/A (measure is Y/N) |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|------|----------------------|

|                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                    |      |                                                                                                            |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|------------------------------------------------------------------------------------------------------------|
| Provider to Patient Exchange | <p>Provide Patients Electronic Access to Their Health Information:</p> <p>For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):</p> <p>(1) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit their health information; and</p> <p>(2) the eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interface (API) in the eligible hospital's or CAH's CEHRT.</p> | <p>The number of patients in the denominator (or patient authorized representatives) who are provided timely access to health information to view online, download and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the eligible hospital's or CAH's CEHRT.</p> | <p>The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p> | None | <p>Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.</p> |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|------------------------------------------------------------------------------------------------------------|

|                                          |                                                                                                                                                                                                                                                                             |                      |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                      |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Public Health and Clinical Data Exchange | Immunization Registry Reporting:<br><br>The eligible hospital or CAH is in active engagement with a PHA to submit immunization data and receive immunization forecasts and histories from the public health immunization registry or immunization information system (IIS). | N/A (measure is Y/N) | N/A (measure is Y/N) | Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the eligible hospital or CAH: (1) Does not administer any immunizations to any of the populations for which data are collected by its jurisdiction's immunization registry or IIS during the EHR reporting period; (2) Operates in a jurisdiction for which no immunization registry or IIS is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no immunization registry or IIS has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period. | N/A (measure is Y/N) |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|

|                                          |                                                                                                                                                                                              |                      |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                      |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Public Health and Clinical Data Exchange | <p>Syndromic Surveillance Reporting:</p> <p>The eligible hospital or CAH is in active engagement with a PHA to submit syndromic surveillance data from an emergency department (POS 23).</p> | N/A (measure is Y/N) | N/A (measure is Y/N) | <p>Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency department; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.</p>                                    | N/A (measure is Y/N) |
| Public Health and Clinical Data Exchange | <p>Electronic Case Reporting:</p> <p>The eligible hospital or CAH is in active engagement with a PHA to submit case reporting of reportable conditions.</p>                                  | N/A (measure is Y/N) | N/A (measure is Y/N) | <p>Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not treat or diagnose any reportable diseases for which data are collected by its jurisdiction's reportable disease system during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.</p> | N/A (measure is Y/N) |

|                                          |                                                                                                                                                                                                                                                                                                                                         |                      |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                      |
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| Public Health and Clinical Data Exchange | Electronic Laboratory Reporting:<br><br>The eligible hospital or CAH is in active engagement with a PHA to submit Electronic Laboratory Reporting results.                                                                                                                                                                              | N/A (measure is Y/N) | N/A (measure is Y/N) | Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the Electronic Laboratory Reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of accepting the specific Electronic Laboratory Reporting standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive Electronic Laboratory Reporting results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period. | N/A (measure is Y/N) |
| Public Health and Clinical Data Exchange | Antimicrobial Use Surveillance:<br><br>The eligible hospital or CAH is in active engagement with CDC's National Health Safety Network (NHSN) to submit Antimicrobial Use data for the EHR reporting period and receives a report from NHSN indicating its successful submission of Antimicrobial Use data for the EHR reporting period. | N/A (measure is Y/N) | N/A (measure is Y/N) | Any eligible hospital or CAH may be excluded from the measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have electronic medication administration record (eMAR)/barcode medication administration (BCMA) electronic records or an admission, discharge, transfer (ADT) system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting.                                                                                                                                                                       | N/A (measure is Y/N) |
| Public Health and Clinical Data Exchange | Antimicrobial Resistance Surveillance:<br><br>The eligible hospital or CAH is in active engagement with                                                                                                                                                                                                                                 | N/A (measure is Y/N) | N/A (measure is Y/N) | Any eligible hospital or CAH may be excluded from the measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | N/A (measure is Y/N) |



|                                          |                                                                                                                                                                                                                                                                                                                                         |                      |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                      |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Public Health and Clinical Data Exchange | Electronic Laboratory Reporting:<br><br>The eligible hospital or CAH is in active engagement with a PHA to submit Electronic Laboratory Reporting results.                                                                                                                                                                              | N/A (measure is Y/N) | N/A (measure is Y/N) | Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the Electronic Laboratory Reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of accepting the specific Electronic Laboratory Reporting standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive Electronic Laboratory Reporting results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period. | N/A (measure is Y/N) |
| Public Health and Clinical Data Exchange | Antimicrobial Use Surveillance:<br><br>The eligible hospital or CAH is in active engagement with CDC's National Health Safety Network (NHSN) to submit Antimicrobial Use data for the EHR reporting period and receives a report from NHSN indicating its successful submission of Antimicrobial Use data for the EHR reporting period. | N/A (measure is Y/N) | N/A (measure is Y/N) | Any eligible hospital or CAH may be excluded from the measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have electronic medication administration record (eMAR)/barcode medication administration (BCMA) electronic records or an admission, discharge, transfer (ADT) system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting.                                                                                                                                                                       | N/A (measure is Y/N) |
| Public Health and Clinical Data Exchange | Antimicrobial Resistance Surveillance:<br><br>The eligible hospital or CAH is in active engagement with                                                                                                                                                                                                                                 | N/A (measure is Y/N) | N/A (measure is Y/N) | Any eligible hospital or CAH may be excluded from the measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | N/A (measure is Y/N) |

|                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                      |                      |                                                                                                                                                                                                                                                                                            |                      |
|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
|                                          | CDC's NHSN to submit Antimicrobial Resistance data for the EHR reporting period and receives a report from NHSN indicating its successful submission of Antimicrobial Resistance data for the EHR reporting period.                                                                                                                                                                                                                                                                                                                                                                  |                      |                      | which data are collected by NHSN during the EHR reporting period; (2) Does not have a laboratory information system (LIS) or ADT system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting. |                      |
| Public Health and Clinical Data Exchange | Public Health Registry Reporting:<br><br>The eligible hospital or CAH is in active engagement with a PHA to submit data to public health registries.                                                                                                                                                                                                                                                                                                                                                                                                                                 | N/A (measure is Y/N) | N/A (measure is Y/N) | None                                                                                                                                                                                                                                                                                       | N/A (measure is Y/N) |
| Public Health and Clinical Data Exchange | Clinical Data Registry Reporting:<br><br>The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.                                                                                                                                                                                                                                                                                                                                                                                                                                            | N/A (measure is Y/N) | N/A (measure is Y/N) | None                                                                                                                                                                                                                                                                                       | N/A (measure is Y/N) |
| Public Health and Clinical Data Exchange | Public Health Reporting Using TEFCA:<br><br>The eligible hospital or CAH (1) Participates as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the <b>Federal Register</b> and on ONC's website); (2) is not suspended; (3) submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; (4) is in active engagement Option 2 (validated data production) with a PHA to transfer | N/A (measure is Y/N) | N/A (measure is Y/N) | None                                                                                                                                                                                                                                                                                       | N/A (measure is Y/N) |

|                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                      |                      |                                                                                                                                                                    |                      |
|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
|                                          | health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; and (5) uses the functions of CEHRT to exchange data with the PHA.                                                                                                                                                                                                                                                                                                             |                      |                      |                                                                                                                                                                    |                      |
| Public Health and Clinical Data Exchange | <p>Unique Device Identifier.*</p> <p>The eligible hospital or CAH uses CEHRT during the EHIR reporting period to electronically capture and store, as one or more discrete data elements within the patient's electronic health record, the complete Unique Device Identifier (UDI), which includes the device identifier and, when present on the device label, the production identifier, for each implantable medical device subject to UDI requirements used for patient care delivery.</p> | N/A (measure is Y/N) | N/A (measure is Y/N) | The eligible hospital or CAH implanted five or fewer medical devices subject to UDI requirements during the calendar year of the applicable EHIR reporting period. | N/A (measure is Y/N) |
| Protect Patient Health Information       | <p>Security Risk Analysis:</p> <p>First, conduct or review a security risk analysis and second, conduct security risk management activities, in accordance with the requirements under 45 CFR 164.308(a)(1)(ii)(A) and (B). Security risk analysis and management activities include addressing the security of data created or maintained by CEHRT (to include encryption), in accordance with 45 CFR 164.312(a)(2)(iv) and 45 CFR</p>                                                         | N/A (measure is Y/N) | N/A (measure is Y/N) | None                                                                                                                                                               | N/A (measure is Y/N) |

|                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                      |                      |      |                      |
|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|------|----------------------|
|                                    | 164.306(d)(3). The encryption implementation specified at 45 CFR 164.312(a)(2)(iv) must be implemented if it is reasonable and appropriate; if encryption is not reasonable and appropriate, then the eligible hospital or CAH would adopt an equivalent alternative measure if it is reasonable and appropriate to do so. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs. |                      |                      |      |                      |
| Protect Patient Health Information | <p>Safety Assurance Factors for EHR Resilience (SAFER) Guides</p> <p>Conduct an annual self-assessment using all eight of the 2025 SAFER Guides at any point during the calendar year in which the EHR reporting period occurs, beginning with the EHR reporting period in CY 2026 and subsequent years.</p>                                                                                                                                                            | N/A (measure is Y/N) | N/A (measure is Y/N) | None | N/A (measure is Y/N) |

\* Signifies a proposal made in this FY 2027 IPPS/LTCH PPS proposed rule that would apply to the EHR reporting period in CY 2027.

\*\* Signifies a proposal made in this FY 2027 IPPS/LTCH PPS proposed rule that would apply to the EHR reporting period in CY 2028 and subsequent years.

**TABLE IX.F.-07. : MEDICARE PROMOTING INTEROPERABILITY PROGRAM  
OBJECTIVES AND MEASURES AND ONC HEALTH IT CERTIFICATION CRITERIA**

| Objective                                 | Measure                                                                            | ONC Health IT Certification Criteria as defined in the following sections of Title 45 CFR                                                                                     | ONC Health IT Certification Criteria Changes If HTI-5 Proposals Are Finalized as Proposed |
|-------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| e-Prescribing                             | e-Prescribing                                                                      | 170.315(b)(3) e-Prescribing                                                                                                                                                   | No change                                                                                 |
|                                           | Query of PDMP                                                                      | 170.315(b)(3) e-Prescribing                                                                                                                                                   | No change                                                                                 |
| Health Information Exchange               | Support Electronic Referral Loops by Sending Health Information*                   | 170.315(b)(1) Transitions of care                                                                                                                                             | Revised                                                                                   |
|                                           | Support Electronic Referral Loops by Receiving and Reconciling Health Information* | 170.315(b)(1) Transitions of care                                                                                                                                             | Revised                                                                                   |
|                                           |                                                                                    | 170.315(b)(2) Clinical information reconciliation and incorporation                                                                                                           | Removed                                                                                   |
| Health Information Exchange (alternative) | HIE Bi-Directional Exchange                                                        | Examples of certified health IT capabilities to support the actions of this measure may include but are <u>not</u> limited to technology certified to the following criteria: |                                                                                           |
|                                           |                                                                                    | 170.315(b)(1) Transitions of care                                                                                                                                             | Revised                                                                                   |
|                                           |                                                                                    | 170.315(b)(2) Clinical information reconciliation and incorporation                                                                                                           | Removed                                                                                   |
|                                           |                                                                                    | 170.315(g)(7) Application access — patient selection                                                                                                                          | Removed                                                                                   |
|                                           |                                                                                    | 170.315(g)(9) Application access — all data request                                                                                                                           | Removed                                                                                   |
|                                           |                                                                                    | 170.315(g)(10) Application access — standardized API for patient and population services                                                                                      | No change                                                                                 |
| Health Information Exchange (alternative) | Enabling Exchange Under TECA                                                       | Examples of certified health IT capabilities to support the actions of this measure may include but are <u>not</u> limited to technology certified to the following criteria: |                                                                                           |
|                                           |                                                                                    | 170.315(b)(1) Transitions of care                                                                                                                                             | Revised                                                                                   |
|                                           |                                                                                    | 170.315(g)(7) Application access — patient selection                                                                                                                          | Removed                                                                                   |
|                                           |                                                                                    | 170.315(g)(9) Application access — all data request                                                                                                                           | Removed                                                                                   |
|                                           |                                                                                    | 170.315(g)(10) Application access — standardized API for patient and population services                                                                                      | No change                                                                                 |

|                                          |                                                                |                                                                                                                                                                               |           |
|------------------------------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Health Information Exchange              | Electronic Prior Authorization*                                | Certified health IT capabilities (that may support the actions of this measure                                                                                                |           |
|                                          |                                                                | 170.315(g)(31) Provider prior authorization API — coverage requirements discovery*                                                                                            | No change |
|                                          |                                                                | 170.315(g)(32) Provider prior authorization API — documentation templates and rules*                                                                                          | No change |
|                                          |                                                                | 170.315(g)(33) Provider prior authorization API — prior authorization support*                                                                                                | No change |
| Provider to Patient Exchange             | Provide patients electronic access to their health information | 170.315(c)(1) View, download, and transmit to 3rd party                                                                                                                       | Revised   |
|                                          |                                                                | 170.315(g)(7) Application access — patient selection                                                                                                                          | Removed   |
|                                          |                                                                | 170.315(g)(9) Application access — all data request                                                                                                                           | Removed   |
|                                          |                                                                | 170.315(g)(10) Application access — standardized API for patient and population services                                                                                      | No change |
| Public Health and Clinical Data Exchange | Immunization registry reporting                                | 170.315(f)(1) Transmission to immunization registries                                                                                                                         | No change |
|                                          | Syndromic surveillance reporting                               | 170.315(f)(2) Transmission to public health agencies — syndromic surveillance                                                                                                 | No change |
|                                          | Electronic case reporting                                      | 170.315(f)(5) Transmission to public health agencies — electronic case reporting                                                                                              | Revised   |
|                                          | Public health registry reporting                               | 170.315(f)(7) Transmission to public health agencies — health care surveys.                                                                                                   | Removed   |
|                                          | Clinical data registry reporting                               | No ONC health IT certification criteria at this time.                                                                                                                         | No change |
|                                          | Public health reporting using IEFCA                            | Examples of certified health IT capabilities to support the actions of this measure may include but are <u>not</u> limited to technology certified to the following criteria: |           |
|                                          |                                                                | 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results                                                                          | No change |
|                                          |                                                                | 170.315(f)(5) Transmission to public health agencies — electronic case reporting                                                                                              | Revised   |
|                                          | Electronic laboratory reporting                                | 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results                                                                          | Revised   |
|                                          | Antimicrobial Use Surveillance                                 | 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting                                                                             | Revised   |

|                                              |                                       |                                                                                                                                    |                      |
|----------------------------------------------|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|----------------------|
|                                              | Antimicrobial Resistance Surveillance | 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting                                  | Revised              |
|                                              | Unique Device Identifier*             | 170.315(a)(14) Implantable device list<br>170.315(g)(10) Application access — standardized API for patient and population services | Removed<br>No change |
| Electronic Clinical Quality measures (eCQMs) | eCQMs for eligible hospitals and CAHs | 170.315(c)(1)                                                                                                                      | No change            |
|                                              |                                       | 170.315(c)(2)                                                                                                                      | No change            |
|                                              |                                       | 170.315(c)(3)(i) and (ii)                                                                                                          | No change            |
| Protect Patient Health Information           | Security Risk Analysis                | No ONC health IT certification criteria at this time.                                                                              | No change            |
|                                              | SAFER Guides                          | No ONC health IT certification criteria at this time.                                                                              | No change            |

\*Signifies a measure with a proposal made in this FY 2027 IPPS/LTCH PPS proposed rule.

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#### 9. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

##### a. Background on Clinical Quality Measurement for Eligible Hospitals and CAHs

Under sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Act and the definition of “meaningful EHR user” under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures (also referred to as electronic clinical quality measures, or eCQMs) selected by CMS using CEHRT as part of the Medicare Promoting Interoperability Program.

As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38479), we intend to continue to align the eCQM reporting requirements and eCQM measure set for the Medicare Promoting Interoperability Program with similar requirements under the Hospital Inpatient Quality Reporting Program, to the extent feasible. Section 1886(n)(3)(B)(i)(I) of the Act requires the Secretary to provide preference for the selection of clinical quality measures that are also used in the Hospital Inpatient Quality Reporting Program or endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (referred to in this rule as the consensus-based entity (CBE)). Furthermore, aligning eCQM reporting requirements between the Medicare Promoting Interoperability Program and the Hospital Inpatient Quality Reporting Program allows for improved

coordination, burden reduction, and the promotion of quality care.

##### b. Proposals To Adopt and Remove eCQMs

As discussed in section IX.B.1., section IX.C.3., section IX.C.4., and section IX.C.8.c. of the preamble of this proposed rule, and in alignment with the Hospital Inpatient Quality Reporting Program, we are proposing to adopt and remove the same eCQMs for the Medicare Promoting Interoperability Program beginning with the CY 2028 reporting period. Specifically, we are proposing to adopt the following two eCQMs in the Medicare Promoting Interoperability Program eCQM measure set from which eligible hospitals and CAHs could self-select to report, beginning with the CY 2028 reporting period: (1) Hospital Harm—Postoperative Venous Thromboembolism; and (2) Advance Care Planning. Additionally, we are proposing to remove the following three eCQMs from the Medicare Promoting Interoperability Program eCQM measure set, beginning with the CY 2028 reporting period: (1) Discharged on Antithrombotic Therapy; (2) Venous Thromboembolism Prophylaxis eCQM; and (3) Intensive Care Unit Venous Thromboembolism Prophylaxis.

We invite public comment on these proposals.

##### c. Proposal To Modify the eCQM Reporting and Submission Requirements

Consistent with our goal to align the eCQM reporting periods and criteria in

the Medicare Promoting Interoperability Program with the Hospital Inpatient Quality Reporting Program, eligible hospitals and CAHs are currently required to annually report data for each required eCQM and three self-selected eCQMs for the CY 2026 reporting period and subsequent years (85 FR 58975 through 58976, 86 FR 45496, 87 FR 49365 through 49367, and 89 FR 69623 through 69624). We are not proposing changes to our previously finalized policy that progressively increases the number of mandatory eCQMs a hospital must report for the CY 2026 reporting period or the CY 2027 reporting period (89 FR 69623 through 69624). In alignment with the Hospital Inpatient Quality Reporting Program, we are proposing changes to the reporting and submission requirements for eCQMs for the Medicare Promoting Interoperability Program beginning with the CY 2028 reporting period. Specifically, we propose to modify the eCQM reporting and submission requirements for the Hospital Harm eCQMs such that beginning with the CY 2028 reporting period these eCQMs would become mandatory for reporting after 2 years of self-selected reporting. Under this proposal, the Hospital Harm—Falls with Injury eCQM and the Hospital Harm—Postoperative Respiratory Failure eCQM would become mandatory for reporting beginning with the CY 2028 reporting period. Consistent with this proposed approach for the Hospital Harm eCQMs (that is, two years of self-selected reporting followed by mandatory reporting in the third year), the proposed Hospital Harm—Postoperative

VTE eCQM would be available for self-selected reporting for the CY 2028 and CY 2029 reporting periods and would become mandatory for reporting beginning with the CY 2030 reporting period, if finalized. We refer readers to section IX.C.8.c. of the preamble of this proposed rule for more detailed discussion in the Hospital Inpatient Quality Reporting Program.

Further, we propose to require mandatory reporting of the Malnutrition Care Score eCQM beginning with the CY

2028 reporting period. The Hospital Harm—Falls with Injury eCQM, the Hospital Harm—Postoperative Respiratory Failure eCQM, and the Malnutrition Care Score eCQM would continue to be available as self-selected measures for the CY 2027 reporting period. These proposed changes are intended to further incentivize improvements in patient safety and nutrition care. We refer readers to section IX.C.8.c. of the preamble of this proposed rule for more detailed

discussion in the Hospital Inpatient Quality Reporting Program about our rationale.

We refer readers to Table IX.F.–9 for the full list of eQMs available by reporting period. Table IX.F.–8 summarizes our proposed policies to modify reporting and submission requirements for eQMs beginning with the CY 2028 reporting period.

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**TABLE IX.F.-8. SUMMARY OF PROPOSED ECQM REPORTING AND SUBMISSION REQUIREMENTS**

| Reporting Period             | Total Number of eQMs Reported | eQMs Required to be Reported                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | eQMs for Self-selection (must report 3)                                                                                                                                                                                                                                                                                                                                      |
|------------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CY 2028                      | Fourteen                      | <ul style="list-style-type: none"> <li>• Safe Use of Opioids—Concurrent Prescribing</li> <li>• Cesarean Birth</li> <li>• Severe Obstetric Complications</li> <li>• Malnutrition Care Score*</li> <li>• Hospital Harm—Severe Hyperglycemia</li> <li>• Hospital Harm—Severe Hypoglycemia</li> <li>• Hospital Harm—Opioid-Related Adverse Events</li> <li>• Hospital Harm—Pressure Injury</li> <li>• Hospital Harm—Acute Kidney Injury</li> <li>• Hospital Harm—Falls with Injury*</li> <li>• Hospital Harm—Postoperative Respiratory Failure*</li> </ul>                                                                  | <ul style="list-style-type: none"> <li>• Anticoagulation Therapy for Atrial Fibrillation/Flutter</li> <li>• Antithrombotic Therapy by the End of Hospital Day Two</li> <li>• Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults</li> <li>• Advance Care Planning**</li> <li>• Hospital Harm—Postoperative Venous Thromboembolism***</li> </ul> |
| CY 2029                      | Fourteen                      | <ul style="list-style-type: none"> <li>• Safe Use of Opioids—Concurrent Prescribing</li> <li>• Cesarean Birth</li> <li>• Severe Obstetric Complications</li> <li>• Malnutrition Care Score*</li> <li>• Hospital Harm—Severe Hyperglycemia</li> <li>• Hospital Harm—Severe Hypoglycemia</li> <li>• Hospital Harm—Opioid-Related Adverse Events</li> <li>• Hospital Harm—Pressure Injury</li> <li>• Hospital Harm—Acute Kidney Injury</li> <li>• Hospital Harm—Falls with Injury*</li> <li>• Hospital Harm—Postoperative Respiratory Failure*</li> </ul>                                                                  | <ul style="list-style-type: none"> <li>• Anticoagulation Therapy for Atrial Fibrillation/Flutter</li> <li>• Antithrombotic Therapy by the End of Hospital Day Two</li> <li>• Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults</li> <li>• Advance Care Planning**</li> <li>• Hospital Harm—Postoperative Venous Thromboembolism***</li> </ul> |
| CY 2030 and subsequent years | Fifteen                       | <ul style="list-style-type: none"> <li>• Safe Use of Opioids—Concurrent Prescribing</li> <li>• Cesarean Birth</li> <li>• Severe Obstetric Complications</li> <li>• Malnutrition Care Score*</li> <li>• Hospital Harm—Severe Hyperglycemia</li> <li>• Hospital Harm—Severe Hypoglycemia</li> <li>• Hospital Harm—Opioid-Related Adverse Events</li> <li>• Hospital Harm—Pressure Injury</li> <li>• Hospital Harm—Acute Kidney Injury</li> <li>• Hospital Harm—Falls with Injury*</li> <li>• Hospital Harm—Postoperative Respiratory Failure*</li> <li>• Hospital Harm—Postoperative Venous Thromboembolism***</li> </ul> | <ul style="list-style-type: none"> <li>• Anticoagulation Therapy for Atrial Fibrillation/Flutter</li> <li>• Antithrombotic Therapy by the End of Hospital Day Two</li> <li>• Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults</li> <li>• Advance Care Planning**</li> </ul>                                                                  |

\* Proposed modification in this proposed rule from self-selected to mandatory reporting beginning with the CY 2028 reporting period.

\*\* Proposed for adoption in this proposed rule as a self-selected eCQM beginning with the CY 2028 reporting period.

\*\*\* Proposed for adoption in this proposed rule as a self-selected eCQM beginning with the CY 2028 reporting period. If this proposal and our proposal to modify the eCQM reporting and submission requirements for Hospital Harm eQMs are finalized, the proposed measure would become mandatory after two years of self-selected reporting beginning with the CY 2030 reporting period.



|                                            |                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| We invite public comment on this proposal. | <p>d. Summary of Previously Finalized and Newly Proposed eCQMs Available for Eligible Hospitals and CAHs To Report Under the Promoting Interoperability Program</p> <p>Table IX.F.–9 summarizes the previously finalized and newly</p> | proposed eCQMs available for eligible hospitals and CAHs to report under the Medicare Promoting Interoperability Program for the specified reporting periods, including whether the measure is mandatory or self-selected as further discussed in section IX.C.8.c. regarding proposed changes to this latter policy. |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**TABLE IX.F.-9 : PREVIOUSLY FINALIZED AND PROPOSED PROMOTING  
INTEROPERABILITY PROGRAM MEASURE SET BY DATA COLLECTION  
METHOD AND REPORTING PERIOD**

| Measure Name                                                                                                                        | CBE Number | CY 2026 | CY 2027 | CY 2028                              | CY 2029                              | CY 2030                              |
|-------------------------------------------------------------------------------------------------------------------------------------|------------|---------|---------|--------------------------------------|--------------------------------------|--------------------------------------|
| Discharged on Antithrombotic Therapy**                                                                                              | 0435e      | *       | *       | Proposed for Removal                 | Proposed for Removal                 | Proposed for Removal                 |
| Anticoagulation Therapy for Atrial Fibrillation/Flutter                                                                             | 0436e      | *       | *       | *                                    | *                                    | *                                    |
| Antithrombotic Therapy by the End of Hospital Day Two                                                                               | 0438e      | *       | *       | *                                    | *                                    | *                                    |
| Venous Thromboembolism Prophylaxis**                                                                                                | 0371e      | *       | *       | Proposed for Removal                 | Proposed for Removal                 | Proposed for Removal                 |
| Intensive Care Unit Venous Thromboembolism Prophylaxis**                                                                            | 0372e      | *       | *       | Proposed for Removal                 | Proposed for Removal                 | Proposed for Removal                 |
| Safe Use of Opioids - Concurrent Prescribing                                                                                        | 3316e      | ✓       | ✓       | ✓                                    | ✓                                    | ✓                                    |
| Hospital Harm—Opioid-Related Adverse Events                                                                                         | 3501e      | *       | ✓       | ✓                                    | ✓                                    | ✓                                    |
| Hospital Harm—Severe Hypoglycemia                                                                                                   | 3503e      | ✓       | ✓       | ✓                                    | ✓                                    | ✓                                    |
| Hospital Harm—Severe Hyperglycemia                                                                                                  | 3533e      | ✓       | ✓       | ✓                                    | ✓                                    | ✓                                    |
| Hospital Harm—Pressure Injury                                                                                                       | 3498e      | *       | *       | ✓                                    | ✓                                    | ✓                                    |
| Hospital Harm—Acute Kidney Injury                                                                                                   | 3713e      | *       | *       | ✓                                    | ✓                                    | ✓                                    |
| Hospital Harm—Falls with Injury***                                                                                                  | 4120e      | *       | *       | Proposed for Mandatory Reporting     | Proposed for Mandatory Reporting     | Proposed for Mandatory Reporting     |
| Hospital Harm—Postoperative Respiratory Failure***                                                                                  | 4130e      | *       | *       | Proposed for Mandatory Reporting     | Proposed for Mandatory Reporting     | Proposed for Mandatory Reporting     |
| Hospital Harm—Postoperative Venous Thromboembolism****                                                                              | 5325e      |         |         | Proposed for Self-selected Reporting | Proposed for Self-selected Reporting | Proposed for Mandatory Reporting     |
| Cesarean Birth                                                                                                                      | 0471e      | ✓       | ✓       | ✓                                    | ✓                                    | ✓                                    |
| Severe Obstetric Complications                                                                                                      | 3687e      | ✓       | ✓       | ✓                                    | ✓                                    | ✓                                    |
| Malnutrition Care Score***                                                                                                          | 3592e      | *       | *       | Proposed for Mandatory Reporting     | Proposed for Mandatory Reporting     | Proposed for Mandatory Reporting     |
| Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient) | 3663e      | *       | *       | *                                    | *                                    | *                                    |
| Advance Care Planning****                                                                                                           | N/A        |         |         | Proposed for Self-Selected Reporting | Proposed for Self-Selected Reporting | Proposed for Self-Selected Reporting |

✓ Measure is mandatory for the specified reporting period.

\* Measure is a self-selected eCQM for the specified reporting period. Hospitals are required to self-select three eCQMs, in addition to all mandatory eCQMs, to submit for the specified reporting period.

\*\* Proposed for removal in this proposed rule beginning with the CY 2028 reporting period.

\*\*\* Proposed modification in this proposed rule from self-selected to mandatory reporting beginning with the CY 2028 reporting period and subsequent years.

\*\*\*\* Proposed for adoption in this proposed rule beginning with the CY 2028 reporting period. We refer readers to section IX.C.8.c. for our proposal to modify reporting and submission requirements for eCQMs; under this proposal the Hospital Harm—Postoperative VTE eCQM would become mandatory after two years of self-selected beginning with the CY 2030 reporting period.

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**X. Other Provisions Included in This Proposed Rule***A. Proposed Changes to the Transforming Episode Accountability Model (TEAM)*

## 1. Background

## a. Purpose

TEAM is a 5-year mandatory alternative payment model tested by the CMS Innovation Center that will begin on January 1, 2026, and end on December 31, 2030. TEAM will test whether an episode-based pricing methodology linked with quality measure performance for select acute care hospitals reduces Medicare program expenditures while preserving or improving the quality of care for Medicare beneficiaries who initiate certain episode categories. Specifically, TEAM will test five surgical episode categories: Coronary Artery Bypass Graft Surgery (CABG), Lower Extremity Joint Replacement (LEJR), Major Bowel Procedure, Surgical Hip/Femur Fracture Treatment (SHFFT), and Spinal Fusion.

As discussed in greater detail in section X.A.1.b. of the preamble of this proposed rule, TEAM was established through notice and comment rulemaking. As a mandatory model, new policies or policy modifications require notice and comment rulemaking. In this proposed rule, we are seeking to make updates to TEAM that include the following modifications:

- Adding new Medicare Severity Diagnosis Related Groups (MS-DRGs) to the spinal fusion episode category.
- Adjusting episode attribution.
- Adjusting the measurement performance periods for certain quality measures.
- Adjusting the construction of the CQS baseline period.
- Capturing Ambulatory Payment Classification (APC) and MS-DRG changes in preliminary target prices.
- Adjusting the construction of the prospective normalization factor.

We are also soliciting public comment on two Requests for Information (RFI) in the following policy areas:

- Ambulatory Surgical Center (ASC) Episodes.
- Voluntary Hospital with Physician Ownership (POH) The policies in this proposed rule reflect our commitment to ensuring TEAM's incentives help to drive beneficiary quality of care improvements and reductions in Medicare spending.

## b. Statutory Authority and Background

Under the authority of section 1115A of the Act, through notice-and-comment

rulemaking, the CMS Innovation Center established TEAM in the FY 2025 IPPS/LTCH PPS final rule that appeared in the August 28, 2024, **Federal Register** (89 FR 69626 through 69879). The intent of TEAM is to improve beneficiary care through financial accountability for episode categories that begin with one of the following procedures: CABG, LEJR, major bowel procedure, SHFFT, and spinal fusion. TEAM will test whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

Under Original Medicare, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the course of an episode of care. Because providers and suppliers are paid for each individual item or service delivered, providers may not be incentivized to invest in quality improvement and care coordination activities. As a result, care may be fragmented, unnecessary, or duplicative. By holding hospitals accountable for all items and services provided during an episode, providers would be better incentivized to coordinate patient care, avoid duplicative or unnecessary services, and improve the beneficiary care experience during care transitions.

Under TEAM, all acute care hospitals, with limited exceptions, located within the Core Based Statistical Areas (CBSAs) that CMS selected for model implementation are required to participate in TEAM. CMS allowed a one-time opportunity for hospitals that participate until the last day of the last performance period in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model or the last day of the last performance year of the Comprehensive Care for Joint Replacement (CJR) Model, that are not located in a mandatory CBSA selected for TEAM participation, to voluntarily opt into TEAM. TEAM includes a 1-year glide path opportunity that allows TEAM participants to ease into full financial risk as well as three different participation tracks to accommodate different levels of financial risk and reward. Track 1 is an upside only risk track available for all TEAM participants in the first performance year and available to safety net hospitals for the first 3 performance years. Track 2 is a two-sided risk track that has lower financial risk and reward, relative to Track 3, and will be available to select TEAM participants in performance

years 2 through 5.<sup>450</sup> Track 3 is a two-sided risk track that has higher financial risk and reward, relative to Track 2, and is available to all TEAM participants in performance years 1 through 5.

Episodes include non-excluded Medicare Parts A and B items and services and begin with an anchor hospitalization or anchor procedure and will end 30 days after hospital discharge. TEAM participants continue to bill Medicare FFS as usual for items and services delivered to beneficiaries in an episode but will receive preliminary target prices for episodes prior to each performance year. Target prices are based on 3 years of baseline data, prospectively trended forward to the relevant performance year, and calculated at the level of Medicare Severity Diagnosis Related Group/Healthcare Common Procedure Coding System (MS-DRG/HCPCS) episode type and region. Target prices also include a discount factor and risk-adjustment. Participants will receive reconciliation (final) target prices that will incorporate a capped retrospective trend factor adjustment and a capped normalization factor.

Performance in the model will be assessed by comparing TEAM participants' actual Medicare FFS spending during a performance year to their reconciliation target price as well as by assessing performance on selected quality measures. TEAM participants may earn a payment from CMS, subject to a quality performance adjustment, if their spending is below the reconciliation target price. TEAM participants may owe CMS a repayment amount, subject to a quality performance adjustment, if their spending was above the reconciliation target price.

**2. TEAM Provisions of This Proposed Rule**

## a. Episodes

## (1) Background

As indicated in the FY 2025 IPPS/LTCH PPS final rule, an episode has two significant dimensions: (1) a clinical dimension that describes which clinical conditions and associated services are included in the episode; and (2) a time dimension that describes the beginning and end of the episode, its length, and when the episode may be cancelled prior to the end of the episode (89 FR 69710). Under TEAM, episodes begin when a beneficiary is admitted for an

<sup>450</sup> TEAM participants eligible for Track 2 include safety net hospitals, rural hospitals, Medicare dependent hospitals, Sole Community Hospitals, and Essential Access Community Hospitals, all defined at § 512.505.

anchor hospitalization or an anchor procedure identified by specific Medicare Severity Diagnosis Related Groups (MS-DRGs) or Healthcare Common Procedure Coding System (HCPCS) codes, identified in 42 CFR 512.525(d). TEAM episodes include all spending for Medicare Parts A and B items and services during the anchor hospitalization or anchor procedure and a 30-day post-discharge period, as described in 42 CFR 512.525(e), with

limited exclusions as outlined in 42 CFR 512.525(f). An episode may be cancelled if the beneficiary (1) does not meet the beneficiary inclusion criteria, as outlined in 42 CFR 512.535; (2) dies during the anchor hospitalization or anchor procedure; or (3) the episode qualifies for the extreme and uncontrollable circumstances policy, as described in 42 CFR 512.537(b)(3).

TEAM tests five episode categories, identified in Table X.A.-01, that

represent high-expenditure, high-volume care delivered to Medicare beneficiaries. These episode categories also generally have a greater proportion of spending in the post-acute period relative to the anchor hospitalization or procedure, that present a greater opportunity to improve care transitions for beneficiaries and reduce unnecessary hospitalizations and emergency care.

**TABLE X.A.-01: EPISODE CATEGORIES AND CORRESPONDING CODES THAT INITIATE AN ANCHOR HOSPITALIZATION OR ANCHOR PROCEDURE**

| Episode Category                      | Anchor Hospitalization Trigger Code (MS-DRG)                       | Anchor Procedure Trigger (HCPCS)     |
|---------------------------------------|--------------------------------------------------------------------|--------------------------------------|
| Coronary Artery Bypass Graft          | 231, 232, 233, 234, 235, or 236                                    | Not Applicable                       |
| Lower Extremity Joint Replacement     | 469, 470, 521, or 522                                              | 27447, 27130, or 27702               |
| Major Bowel Procedure                 | 329, 330, or 331                                                   | Not Applicable                       |
| Surgical Hip Femur Fracture Treatment | 480, 481, or 482                                                   | Not Applicable                       |
| Spinal Fusion                         | 402, 426, 427, 428, 429, 430, 447, 448, 450, 451, 471, 472, or 473 | 22551, 22554, 22612, 22630, or 22633 |

## (2) Proposed Changes to Spinal Fusion Episode Category

Generally, CMS assesses MS-DRG classification changes on an annual basis with the fiscal year IPPS rulemaking cycle. These changes may result in the addition, modification, or deletion of MS-DRGs. Since inpatient episodes in TEAM rely on MS-DRG codes to identify when an anchor hospitalization is initiated, any changes to the MS-DRGs included in TEAM may affect episode volume and ultimately the number of beneficiaries included in the model. As described in section II.C of the preamble of this proposed rule, there are proposals to change certain MS-DRGs that affect the spinal fusion episode category in TEAM. Specifically, three new MS-DRGs are being proposed to better classify beneficiary acuity and resource utilization for a subset of spinal fusion procedures. If these new MS-DRGs are finalized, we propose to make conforming changes in TEAM, therefore we propose at

§ 512.525(d)(4)(i) that starting on October 1, 2026, MS-DRGs 523, 524, and 525 would be added to the spinal fusion episode category that would initiate a spinal fusion anchor hospitalization. We also propose at § 512.505 to update the spinal fusion definition to include these three new MS-DRGs. This means the other spinal fusion MS-DRGs remain unchanged and would initiate a spinal fusion anchor hospitalization starting on January 1, 2026. We believe it's important to include these proposed new MS-DRGs in TEAM so that hospitals can continue to have sufficient spinal fusion episode volume to pursue efficiencies in care

delivery, spread financial risk, and increase the potential to maximize beneficiaries access to value-based care. Further, not including these proposed new MS-DRGs may reduce the scale and create evaluation challenges for the spinal fusion episode category. Lastly, we also believe it's important to capture proposed MS-DRG updates in TEAM to reflect current coding standards, ensuring consistency with IPPS policies.

We considered, but are not proposing, not to update the MS-DRGs in TEAM for the spinal fusion episode category. This would mean that only the spinal fusion MS-DRGs that remain unchanged would initiate a spinal fusion anchor hospitalization in TEAM. While this approach would minimize change during the model test, episode volume would remain a concern. Additionally, we believe it is also not a feasible long-term approach because it's not responsive to Medicare policy changes and prohibits beneficiaries from accessing the benefits of the model.

We seek comment on our proposals at § 512.505 to update the spinal fusion definition and at § 512.525(d)(4)(i) to add MS-DRGs 523, 524, and 525 to the spinal fusion category.

## (3) Proposed Changes to Episode Attribution

In section X.C. of the preamble of this proposed rule, the Comprehensive Care for Joint Replacement Expanded (CJR-X) Model is being proposed as an expanded phase II model test under Section 1115A(c) of the Act. Similar to TEAM, CJR-X would be a mandatory episode-based payment model for acute care hospitals with a focus on Lower Extremity Joint Replacement (LEJR)

episodes. Both TEAM and CJR-X test LEJR episodes, however TEAM tests a 30-day post-discharge period episode length while CJR-X would test a 90-day post-discharge period episode length. Given the model similarities and our desire to assess differences in outcomes between these two episode durations, the CJR-X model is proposing to exclude TEAM participants from participating in CJR-X, as described in section X.C.2.b.(2)(i) of the preamble of this proposed rule. While this exclusion would prevent a TEAM participant from being a CJR-X participant, it does not address instances where a beneficiary is in a CJR-X episode and receives care at a TEAM participant during the CJR-X 90-day post-discharge period. Therefore, we propose at § 512.537(b)(4) that if a beneficiary in a CJR-X episode has a procedure performed at a TEAM hospital that would initiate a TEAM episode during the CJR-X 90-day post-discharge period, then that procedure would not initiate a TEAM episode or be attributed to the TEAM participant and the spending from that procedure would be included in the CJR-X episode. We note that while this instance would result in the TEAM participant not being attributed the episode, the procedure and its associated spending would be included in TEAM target price construction, which relies on average episode spending and average trends across all MS-DRG/HCPCS region combinations. As noted in section X.C.2.(h)(2) of the preamble of this proposed rule, we considered TEAM precedence in this situation and dropping the CJR-X episode to initiate a TEAM episode to

support episode volume in TEAM, but we believe it is important to hold the hospital where the anchor hospitalization or anchor procedure took place accountable for spending and care coordination throughout the episode, especially given the investments that hospitals employ to manage a beneficiary's care. We believe this policy would avoid duplicative calculations for the same procedure in a model that is similar in overall design.

We seek comment on our proposals at § 512.537(b)(4) to not attribute an episode to a TEAM participant if the beneficiary is in a CJR–X episode and has a procedure performed at a TEAM participant that would initiate an episode during the CJR–X 90-day post-discharge period.

#### b. Quality Measures

##### (1) Background

As discussed in the FY25 and FY26 IPPS/LTCH PPS final rule (89 FR 68986 and 90 FR 36536), Medicare payment policy continues to move away from fee-for-service (FFS) payments that are not linked to quality of care. As previously noted in the prior rules, through the Medicare Modernization Act and the Affordable Care Act, we have implemented specific IPPS programs like the Hospital Inpatient Quality Reporting (IQR) Program (section 1886(b)(3)(B)(viii) of the Act), the Hospital Outpatient Quality Reporting (OQR) Program (section 1833(t)(17)(C) of the Act), the Hospital Value-Based Purchasing (VBP) Program (subsection (o) of section 1886), the Hospital-Acquired Condition (HAC) Reduction Program (subsection (q) of section 1886), and the Hospital Readmissions Reduction Program (subsection (p) of section 1886), where payment may reflect the quality of care delivered to Medicare beneficiaries or be impacted by the reporting of quality measures.

TEAM quality measures focus on care coordination, patient safety, and patient-reported outcomes (PROs), which are areas critical to patients undergoing acute procedures. To streamline reporting in this mandatory model, we align quality measures in TEAM with those used in existing CMS models and reporting programs wherever feasible. TEAM participants

will not submit separate quality data to CMS for TEAM. Instead, CMS will utilize data already reported through established CMS quality reporting programs, eliminating duplicate reporting requirements. TEAM's finalized set of quality measures are used to calculate the Composite Quality Score (CQS). The CQS will be combined with the TEAM participants' reconciliation amount during the reconciliation process to tie quality performance to payment. We proposed and finalized seven quality measures due to their: (1) alignment with the goals of TEAM; (2) hospitals' familiarity with the measures due to their use in other CMS hospital quality programs, including the Hospital IQR, OQR and HAC Reduction Programs; and (3) alignment to CMS priorities, including the CMS National Quality Strategy, which has goals that support safety, outcomes, and engagement. We believe these quality measures reflect these goals and accurately measure hospitals' level of achievement on such goals.

The measures are—

- For all TEAM inpatient episodes in PY1–PY5: Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) Measure with Claims and Electronic Health Record Data (CMIT ID #356), claims-only for PY1 and full hybrid for PY2–PY5;

- For all TEAM inpatient episodes in PY1: CMS Patient Safety and Adverse Events Composite (CMS PSI–90) (CMIT ID #135);

- For all TEAM inpatient LEJR episodes in PY1–PY5: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618);

- For all TEAM inpatient episodes in PY2–PY5: Hospital Harm—Falls with Injury (CMIT ID #1518);

- For all TEAM inpatient episodes in PY2–PY5: Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788);

- For all TEAM inpatient episodes in PY2–PY5: Thirty-day Risk—Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134); and

- For all TEAM outpatient LEJR and Spinal Fusion episodes in PY3–PY5:

Information Transfer Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM) (CMIT ID #1797).

We believe the TEAM quality measure set provides CMS with sufficient measures to monitor quality and to calculate scoring on quality performance. As stated in the FY25 and FY26 IPPS/LTCH PPS final rules (89 FR 68986 and 90 FR 36536), we may adjust the measure set in future performance years via rulemaking if we determine those adjustments to be appropriate at the time.

##### (2) Proposed Measurement Performance Periods for Certain Quality Measures

As stated previously, TEAM aims to, whenever possible, align with existing reporting requirements so as not to introduce additional burden to participants. In the FY25 IPPS/LTCH PPS final rule (89 FR 68986), we finalized the Hospital Harm—Falls with Injury, Hospital Harm—Postoperative Respiratory Failure, and Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) and stated these measures would align with the hospital reporting programs. At that time, we stated our intent to align these measures with the performance periods used in the Hospital IQR Program. However, we did not propose or finalize the specific measurement performance periods for these measures within TEAM.

In this proposed rule, we propose establishing measurement performance periods for these three quality measures. For Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure, we propose alignment with the Hospital IQR Program's calendar year reporting requirements, utilizing a one-year measurement performance period. For ISCMR, we propose alignment with the Hospital IQR Program's two-year rolling measurement performance period. Table X.A–02 displays the proposed measurement performance periods for these specific quality measures in TEAM. We believe these measurement performance periods are consistent with other CMS quality reporting programs and therefore would help minimize TEAM participant confusion.

**TABLE X.A.-02: PROPOSED QUALITY MEASUREMENT PERFORMANCE PERIODS**

| Quality Measure                                                                                             | TEAM PERFORMANCE YEAR (PY) QUALITY MEASUREMENT PERFORMANCE PERIOD |                                     |                                     |                                     |
|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
|                                                                                                             | PY2 Performance Period                                            | PY3 Performance Period              | PY4 Performance Period              | PY5 Performance Period              |
| Hospital Harm—Falls with Injury (CMIT ID #1518)                                                             | January 1, 2027 – December 31, 2027                               | January 1, 2028 – December 31, 2028 | January 1, 2029 – December 31, 2029 | January 1, 2030 – December 31, 2030 |
| Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788)                                             | January 1, 2027 – December 31, 2027                               | January 1, 2028 – December 31, 2028 | January 1, 2029 – December 31, 2029 | January 1, 2030 – December 31, 2030 |
| Thirty-day Risk—Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134) | July 1, 2024 – June 30, 2026                                      | July 1, 2025 – June 30, 2027        | July 1, 2026 – June 30, 2028        | July 1, 2027 – June 30, 2029        |

We seek comment on the proposed measurement performance period timeframes for TEAM performance years 2 through 5 for the Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure, and ISCMR quality measures.

### (3) Proposed Changes to TEAM CQS Baseline Period Methodology

In the FY25 IPPS/LTCH PPS final rule (89 FR 68986), we established fixed CQS baselines for calculating CQS performance that would remain constant throughout the model's duration, using calendar year (January–December) CQS baseline periods for all quality measures. The CQS baselines are national distributions of quality measure scores against which TEAM participants are ranked. After evaluating this approach and considering alignment with existing CMS hospital quality reporting programs, we are proposing two changes to the CQS baseline methodology: (1) establishing a sliding historical CQS baseline methodology and (2) aligning CQS baseline periods with the CMS hospital reporting program timeframes for specific measures that are currently not aligned. We propose at § 512.547(a)(1)–(3) replacing the current fixed CQS baseline approach with a sliding historical CQS baseline methodology for all quality measures except the CMS PSI–90 measure which applies only in TEAM PY1 and therefore does not require advancement of baseline periods beyond that performance year. The proposal to change to a sliding historical CQS baseline would be effective beginning with TEAM PY1. Under this proposed approach, CQS baselines would be calculated using a rolling window of historical performance data that updates annually, rather than remaining fixed throughout the model's tenure. This approach would allow CQS baselines to evolve with improvements in care delivery, providing a responsive quality assessment framework.

Considering the proposed shift from fixed to sliding historical CQS baselines, we also propose at § 512.547(a)(1)–(3) to update the baseline periods from a calendar year to a July to June period for the Hybrid HWR, CMS PSI–90, THA/TKA PRO–PM, and the ISCMR measures. Specifically, we propose to align the CQS baseline periods with the hospital program required measurement periods of July–June timeframe rather than the previously finalized calendar year (January–December) periods. This proposed alignment is consistent with the Hospital IQR and HAC programs requirement of July–June measurement periods. Aligning TEAM CQS baseline periods with these established timeframes ensures consistency and reduces confusion. This proposal does not affect the Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure or the Information Transfer PRO–PM, which will continue to use calendar year CQS baseline periods as originally finalized, consistent with their respective hospital reporting program requirements. These measures maintain calendar year CQS baseline periods because their respective hospital reporting program requirements utilize calendar year measurement periods, ensuring consistency between TEAM CQS baselines and the established reporting infrastructure for these specific measures. Additionally, aligning the CQS baseline periods with existing hospital measure timeframes ensures that the necessary data are available and validated according to established timelines. Using the same measurement periods for the existing hospital reporting and TEAM CQS baselines periods leverages this existing data infrastructure and ensures timely availability of baseline data for CQS calculations.

We believe it is important to implement this alignment beginning in TEAM PY1 and to apply it consistently throughout the duration of the model. Beginning this alignment in TEAM PY1

avoids introducing a mid-model change in CQS baseline period timeframes that could create confusion and complicate longitudinal performance assessment. It also ensures that TEAM participants' quality performance is evaluated under a single, transparent methodological framework for the entire duration of the model. In addition, because certain TEAM PY1 measures are not calculated on a calendar-year basis within their respective hospital reporting programs, it would be operationally challenging to re-specify and recalculate these measures solely for TEAM. Aligning TEAM CQS baseline periods with the Hospital IQR and HAC Reduction Program timeframes from the start of the model leverages validated data already calculated for existing programs and minimizes TEAM participant confusion.

We also considered an alternative approach under which the transition from fixed CQS baselines to the sliding historical CQS baseline methodology would begin in TEAM PY2 rather than TEAM PY1. Under this alternative, TEAM PY1 would continue to use the fixed CQS baseline methodology finalized in the FY25 IPPS/LTCH PPS final rule, and the sliding historical CQS baseline methodology (including the July through June baseline period alignment described above) would begin with TEAM PY2 and apply for the remainder of the model. Under this alternative, all CQS baseline periods and methodologies finalized in the FY25 IPPS/LTCH PPS final rule would apply unchanged for TEAM PY1, and the July through June baseline alignment and sliding historical methodology would first apply to TEAM PY2 measurement and CQS calculations. We considered this alternative because beginning the transition in TEAM PY2 could reduce operational and participant risk associated with implementing a baseline methodology change at model launch. Specifically, this risk refers to the potential for operational disruptions, such as insufficient time for participants

to adapt systems and processes to the new methodology, as well as the possibility that participants may not have adequate time to understand, prepare for, and respond to changes in how their quality performance is assessed beginning in TEAM PY1. However, beginning in TEAM PY2 would introduce a mid-model change in baseline methodology, which could create participant confusion and complicate longitudinal performance assessment across performance years. We seek comment on whether beginning the transition to the sliding historical CQS baseline methodology in TEAM PY2, rather than TEAM PY1, would be preferable.

We recognize that updating to the proposed CQS baseline periods beginning in TEAM PY1 means that different months of performance may be reflected in the CQS baseline compared to a calendar-year approach. For example, if a hospital's performance improved during the latter half of calendar year (CY) 2025, those improvements would be included under the proposed July through June CQS baseline period rather than excluded based solely on a calendar-year cutoff.

While this proposed change in baseline timeframe could result in differences in PY1 CQS scoring compared to a CY CQS baseline, improved performance captured within the aligned reporting timeframe would be incorporated as the proposed sliding historical CQS baseline updates in subsequent performance years. See Table X.A–03 for the proposed CQS baseline periods.

Under the proposed approach, the Hybrid HWR measure will use the same CQS baseline period (July 1, 2025 through June 30, 2026) for both TEAM PY2 and PY3. This is necessary because the measure transitions from claims-only methodology in TEAM PY1 to hybrid methodology beginning in TEAM PY2. To ensure valid performance assessment, each methodology requires its own CQS baseline period using comparable data. TEAM PY1 will use a claims-only CQS baseline (July 1, 2024 through June 30, 2025), while TEAM PY2 will establish the hybrid CQS baseline (July 1, 2025 through June 30, 2026). TEAM PY3 maintains the same CQS baseline period as TEAM PY2 because it serves as the initial reference point for the proposed sliding historical CQS baseline methodology, which then

advances annually starting in TEAM PY4 (July 1, 2026 through June 30, 2027) and PY5 (July 1, 2027 through June 30, 2028). Similarly, under this proposed approach, the THA/TKA PRO–PM will use the same CQS baseline period (July 1, 2024 through June 30, 2025) for both TEAM PY1 and PY2. This approach is necessary because July 1, 2024 through June 30, 2025 represents the first mandatory reporting period for this measure in the Hospital IQR Program. Using this initial reporting period as the CQS baseline for both TEAM PY1 and PY2 ensures the baseline is established using complete, validated data. Beginning in TEAM PY3, the THA/TKA PRO–PM CQS baseline advances to July 1, 2025 through June 30, 2026, which serves as the initial reference point for the proposed sliding historical CQS baseline methodology. The CQS baseline then advances annually for TEAM PY4 (July 1, 2026 through June 30, 2027) and PY5 (July 1, 2027 through June 30, 2028), consistent with the proposed sliding historical CQS baseline approach.

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**TABLE X.A–03: PROPOSED CQS BASELINE PERIODS**

| Quality Measure                                                                                                                               | TEAM PERFORMANCE YEAR (PY) QUALITY MEASURE CQS BASELINE PERIODS |                                           |                                           |                                           |                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------|-------------------------------------------|-------------------------------------------|-------------------------------------------|
|                                                                                                                                               | PY1 CQS Baseline Period                                         | PY2 CQS Baseline Period                   | PY3 CQS Baseline Period                   | PY4 CQS Baseline Period                   | PY5 CQS Baseline Period                   |
| Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) Measure with Claims and Electronic Health Record Data (CMIT ID #356)                  | July 1, 2024 through June 30, 2025                              | July 1, 2025 through June 30, 2026        | July 1, 2025 through June 30, 2026        | July 1, 2026 through June 30, 2027        | July 1, 2027 through June 30, 2028        |
| CMS Patient Safety and Adverse Events Composite (CMS PSI-90) (CMIT ID #135)                                                                   | July 1, 2023 through June 30, 2025                              | N/A                                       | N/A                                       | N/A                                       | N/A                                       |
| Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618) | July 1, 2024, through June 30, 2025                             | July 1, 2024, through June 30, 2025       | July 1, 2025 through June 30, 2026        | July 1, 2026 through June 30, 2027        | July 1, 2027 through June 30, 2028        |
| Hospital Harm—Falls with Injury (CMIT ID #1518)                                                                                               | N/A                                                             | January 1, 2026 through December 31, 2026 | January 1, 2027 through December 31, 2027 | January 1, 2028 through December 31, 2028 | January 1, 2029 through December 31, 2029 |
| Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788)                                                                               | N/A                                                             | January 1, 2026 through December 31, 2026 | January 1, 2027 through December 31, 2027 | January 1, 2028 through December 31, 2028 | January 1, 2029 through December 31, 2029 |
| Thirty-day Risk—Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134)                                   | N/A                                                             | July 1, 2023 through June 30, 2025        | July 1, 2024 through June 30, 2026        | July 1, 2025 through June 30, 2027        | July 1, 2026 through June 30, 2028        |
| Information Transfer Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM) (CMIT ID #1797)                         | N/A                                                             | N/A                                       | January 1, 2027 through December 31, 2027 | January 1, 2028 through December 31, 2028 | January 1, 2029 through December 31, 2029 |

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We believe that adopting sliding historical baselines for CQS measurement offers several advantages over the current fixed baseline

approach. Specifically, a sliding historical CQS baseline methodology would enable TEAM to capture and reflect evolving trends in quality

performance over time. As quality improvement initiatives advance, this baseline approach would ensure that performance benchmarks remain

relevant and responsive to these changes. This approach also acknowledges that quality performance is dynamic, requiring evolving baselines to reflect current care standards. Additionally, for the Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure, which are self-selected voluntary reporting measures in the Hospital IQR Program, the proposed sliding historical CQS baseline approach ensures that baselines remain representative of the current reporting population over time. Further, it would ensure performance expectations continue to challenge TEAM participants to improve, rather than meet static targets. We acknowledge that, similar to the concurrent CQS baseline approach discussed below, the sliding historical CQS baseline methodology also presents challenges in tracking long-term progress from the start of the model because the baseline updates annually. However, we believe the proposed sliding historical CQS baseline approach mitigates this concern by using historical data rather than contemporaneous data, in most instances, providing greater stability and predictability while still maintaining relevant performance benchmarks. The proposed sliding historical CQS baseline methodology would align with the target price baseline approach used in TEAM, which rolls forward annually, creating a more coherent performance assessment framework for participating hospitals. This alignment would eliminate the disconnect where cost performance is evaluated against recent benchmarks while quality performance is measured against a static historical reference point, making it easier for TEAM participants to understand the relationship between quality and cost metrics. The parallel baseline structures would enable hospitals to develop improvement strategies that address both quality and cost objectives simultaneously.

We propose implementing the sliding historical CQS baseline methodology beginning with TEAM PY1. We believe beginning implementation of this methodology change in TEAM PY1 is appropriate for several reasons. TEAM PY1 CQS calculations and reconciliation will not occur until Fall 2027. This allows the implementation of this methodology before the calculations occur. Also, all TEAM participants were able to select Track 1 for TEAM PY1 and participants who did not actively select a track were assigned to Track 1 by default. Track 1 does not involve

downside financial risk during TEAM PY1. Additionally, the proposed changes align CQS baseline timeframes with existing hospital reporting program requirement timeframes, meaning hospitals are already collecting and validating data during these timeframes for reporting purposes. Additionally, implementing the proposed sliding historical CQS baseline approach beginning in TEAM PY1 ensures consistent CQS baseline methodology throughout the model's duration and avoids mid-model transitions that could create confusion or complicate performance tracking. This proposed approach, starting in TEAM PY 1, provides participants with clarity and predictability regarding how their quality performance will be assessed throughout all performance years. This consistency supports participants' ability to develop and implement long-term quality improvement strategies that align with both TEAM goals and existing hospital quality reporting requirements.

We considered, but are not proposing, the implementation of a rolling concurrent CQS baselines for quality measures throughout all TEAM performance years. Under a rolling concurrent CQS baseline methodology, the CQS baseline for a given TEAM performance year would be identical to the applicable TEAM measurement period for that year. In other words, the national distribution of measure performance scores against which TEAM participants are ranked would be derived from contemporaneous performance-year data.

This concurrent baseline methodology would require quality performance benchmarks to be recalculated annually using contemporaneous data. For each performance year, the national distribution of measure performance, including risk-adjusted scores, expected-value parameters, and national averages specified in the measure methodology, would be recalibrated based on that same performance year's data before CQS scoring is finalized.

While the proposed sliding historical CQS baseline approach also recalculates benchmarks annually, it uses historical data, in most instances, rather than contemporaneous data. In this context, the reference to "in most instances" reflects that, under the proposed sliding historical approach, the CQS baseline for a given TEAM performance year would generally be based on a completed historical measurement period that precedes the applicable performance year, as reflected in Table X.A–03. For certain measures and performance years identified in Table

X.A–03, however, the same CQS baseline period may apply to more than one performance year or may rely on the first available validated measure reporting period to ensure methodological consistency and the use of complete, validated data.

A concurrent CQS baseline approach offers several advantages, such as capturing real-time performance, encouraging continuous quality improvement, and addressing concerns about outdated benchmarks. In addition, since concurrent CQS baselines compare quality measure scores to baseline scores from the same year, the measure scores and baseline scores are calculated using the same methodology. This methodological alignment is particularly relevant for TEAM quality measures that incorporate expected values with formulas that are recalibrated annually and rely on national averages of hospitals' performance in that year.

However, under a concurrent CQS baseline, improvement would always be assessed relative to a moving CQS baseline. A concurrent CQS baseline, like a sliding historical CQS baseline, would introduce uncertainty for participants because final CQS baseline calculations, including risk adjustment coefficients and national averages used in mapping raw measure scores, would not be available in advance of the applicable performance year. Because the national distribution would be constructed from the same performance-year data, participants would not know the final percentile thresholds or scaling parameters until after the measurement period concludes and national data are finalized.

We recognize that similar timing limitations apply under the sliding historical CQS baseline approach, given the lag between baseline construction and finalization of national performance data. We recognize that several limitations apply to both the concurrent and proposed sliding historical CQS baseline approaches. However, because the proposed sliding historical CQS baseline relies on completed historical data, in most instances, rather than contemporaneous data, it may provide comparatively greater stability relative to a fully concurrent CQS baseline approach. Although we are not proposing a concurrent CQS baseline methodology, we are considering this approach and we seek comment on its potential implementation. Additionally, we are considering whether such an approach, if adopted, should begin in TEAM PY1 or TEAM PY2, and we seek comment on those timing options. Beginning in TEAM PY1 would avoid a



mid-model change in CQS baseline methodology and would allow quality performance to be assessed under a single methodological framework for the duration of the model. Beginning in TEAM PY2 could reduce implementation risk at model launch by

providing additional time for participants to operationalize the methodology and prepare for changes in quality performance assessment. We seek comment on whether a concurrent CQS baseline methodology would be preferable to the proposed sliding

historical CQS baseline methodology and, if so, whether implementation should begin in TEAM PY1 or TEAM PY2. See Table X.A.04.

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**TABLE X.A.-04: CONCURRENT MEASUREMENT PERIODS & CQS BASELINE PERIODS**

| Quality Measure                                                                                                                               | PY1<br>Measurement<br>Period & CQS<br>Baseline<br>Period | PY2<br>Measurement<br>Period & CQS<br>Baseline<br>Period | PY3<br>Measurement<br>Period & CQS<br>Baseline<br>Period | PY4<br>Measurement<br>Period & CQS<br>Baseline<br>Period | PY5<br>Measurement<br>Period & CQS<br>Baseline<br>Period |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|
| Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) Measure with Claims and Electronic Health Record Data (CMIT ID #356)                  | July 1, 2024 through June 30, 2025 (claims-only)         | July 1, 2025 through June 30, 2026 (hybrid)              | July 1, 2026 through June 30, 2027 (hybrid)              | July 1, 2027 through June 30, 2028 (hybrid)              | July 1, 2028 through June 30, 2029 (hybrid)              |
| CMS Patient Safety and Adverse Events Composite (CMS PSI-90) (CMIT ID #135)                                                                   | July 1, 2023 through June 30, 2025                       | N/A                                                      | N/A                                                      | N/A                                                      | N/A                                                      |
| Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618) | July 1, 2024 through June 30, 2025                       | July 1, 2025 through June 30, 2026                       | July 1, 2026 through June 30, 2027                       | July 1, 2027 through June 30, 2028                       | July 1, 2028 through June 30, 2029                       |
| Hospital Harm—Falls with Injury (CMIT ID #1518)                                                                                               | N/A                                                      | January 1, 2027 through December 31, 2027                | January 1, 2028 through December 31, 2028                | January 1, 2029 through December 31, 2029                | January 1, 2030 through December 31, 2030                |
| Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788)                                                                               | N/A                                                      | January 1, 2027 through December 31, 2027                | January 1, 2028 through December 31, 2028                | January 1, 2029 through December 31, 2029                | January 1, 2030 through December 31, 2030                |
| Thirty-day Risk—Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134)                                   | N/A                                                      | July 1, 2024 through June 30, 2026                       | July 1, 2025 through June 30, 2027                       | July 1, 2026 through June 30, 2028                       | July 1, 2027 through June 30, 2029                       |
| Information Transfer Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM) (CMIT ID #1797)                         | N/A                                                      | N/A                                                      | January 1, 2028 through December 31, 2028                | January 1, 2029 through December 31, 2029                | January 1, 2030 through December 31, 2030                |

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We considered, but are not proposing at this time, an alternative approach that would maintain a fixed historical CQS baseline methodology while changing the CQS baseline periods from calendar year to July through June timeframes for the Hybrid HWR, CMS PSI-90, THA/TKA PRO-PM, and the ISCMR measures. Under this alternative fixed CQS baseline approach with updated timeframes, the Hybrid HWR CQS

baseline would be established concurrently with the measurement performance period for TEAM PY1 and would be July 1, 2024 through June 30, 2025, using claims only data and would be updated once more for TEAM PY2 and would be July 1, 2025 through June 30, 2026, using hybrid data to account for the measure's transition from claims-only to hybrid methodology, after which it would remain fixed for TEAM PY3

through PY5. The CMS PSI-90 measure, which is only used in TEAM PY1, would have a CQS baseline period of July 1, 2023 through June 30, 2025, concurrent with its TEAM PY1 measurement period. The THA/TKA PRO-PM would have a concurrent CQS baseline and measurement period for TEAM PY1 of July 1, 2024 through June 30, 2025, which would then remain fixed throughout TEAM PY2 through

PY5. Similarly, the ISCMR measure CQS baseline would be July 1, 2023 through June 30, 2025 and remain fixed for TEAM PY2 through PY5. The Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure CQS baselines would remain calendar year 2026 (January 1, 2026–December 31, 2026) for TEAM PY2 through PY5 and the Information Transfer PRO–PM CQS baseline would remain calendar year 2027 (January 1, 2027–December 31, 2027) for TEAM PY3 through PY5.

The fixed historical CQS baseline approach has several benefits. It offers stable targets that provide greater certainty for participants, as performance benchmarks are known in advance whenever possible. This approach facilitates tracking of long-term quality improvement goals from the start of the model and eliminates the need for annual CQS baseline recalculations, reducing administrative complexity compared to sliding historical CQS baselines. However, we determined that the fixed historical CQS baseline approach presents significant disadvantages. The fixed CQS baselines can become outdated and less reflective of current performance conditions over time. Fixed CQS baselines may also reduce incentives for continuous improvement once participants meet initial targets. Additionally, data anomalies, such as missing or incomplete data from the CQS baseline period, cannot be adjusted under a fixed CQS baseline approach, which could result in inequitable performance assessments throughout the model's duration. These limitations led us to propose the sliding historical CQS baseline methodology instead, which we believe better supports ongoing quality improvement and maintains relevant performance benchmarks throughout the model.

We seek comment on our proposal at § 512.547(a)(1)–(5) for the proposed changes to the CQS baseline methodology in TEAM to include the transition from fixed CQS baseline periods to sliding historical CQS baselines periods and the change from calendar year to July to June timeframe for the Hybrid HWR, CMS PSI–90, THA/TKA PRO–PM, and ISCMR measures. We also seek comment on whether beginning the transition to the sliding historical CQS baseline methodology in TEAM PY2, rather than TEAM PY1, would be preferable. We also seek comment on whether either a fixed historical CQS baseline methodology or a concurrent CQS baseline methodology, each incorporating the updated July through June timeframes

for applicable measures as described above, would be preferable to the proposed sliding historical CQS baseline methodology. With respect to the concurrent CQS baseline methodology specifically, we seek comment on whether, if adopted, implementation should begin in TEAM PY1 or TEAM PY2.c. Pricing Methodology

#### (1) Background

As finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), TEAM participants will be provided with target prices for each MS–DRG/HCPCS episode type. These target prices will be calculated using 3 years of rolling baseline episode spending, trended forward with 2 additional historical years to the performance year, at the level of MS–DRG/HCPCS episode type and region, with updates to be made using the performance year data during the reconciliation process. The regions are defined as the nine U.S. census divisions and the MS–DRG/HCPCS episode type is based on the episode categories that will be tested in the model: Coronary Artery Bypass Graft (CABG), Lower Extremity Joint Replacement (LEJR), Major Bowel Procedure, Surgical Hip Femur Fracture Treatment (SHFFT), and Spinal Fusion.

Episode spending will be capped at the 99th percentile for each of the 29 MSDRG/HCPCS episode types and 9 regions, and the benchmark price will be calculated as the average capped and standardized spending in the most recent baseline year dollars for each MS–DRG/HCPCS episode type in each region, resulting in 261 benchmark prices. Benchmark prices will be calculated using all hospitals in a region, regardless of TEAM participation status. CMS will apply a prospective trend factor and a discount factor to benchmark prices. During reconciliation, these preliminary target prices will be modified by updating the trend (subject to a cap) and normalization factor (subject to a cap) and by adjusting for each participant's realized performance year case mix.

Risk adjustment factors will be calculated and made available to TEAM participants prior to the start of each performance year, so TEAM participants will be able to use them to estimate their episode-level target prices. Risk adjusters finalized in the FY 2025 IPPS/LTCH PPS final rule and FY 2026 IPPS/LTCH PPS final rule include age group, Hierarchical Condition Category (HCC) count, and beneficiary economic risk, as well as episode category-specific HCC adjusters and hospital-level adjusters including a hospital bed size factor and

a safety net hospital factor. The risk adjustment factors will be calculated at the MS–DRG/HCPCS level using a weighted linear regression where episodes are weighted differentially based on whether they belong to year 1, 2, or 3 of the baseline periods. As finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), episodes from baseline year 1 will be weighted at 17 percent, baseline year 2 at 33 percent, and baseline year 3 at 50 percent. The risk adjustment factors will be fixed and applied to performance year episodes at reconciliation based on the realized case mix of the TEAM Participant in the performance year.

After risk adjusting for the performance year case-mix, CMS will normalize the target prices to ensure that the average of the total risk-adjusted preliminary target price does not exceed the average of the total non-risk adjusted preliminary target price. The final normalization factor will be calculated as the mean of the benchmark price for each MS–DRG/HCPCS episode type and region divided by the mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type and region. As finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) it will be capped should this ratio exceed  $\pm 5$  percent of the prospective normalization factor. The final target prices will include a retrospective trend factor, which will be capped at being within 3 percent of the prospective trend, as finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986). The retrospective trend factor will be calculated as the average capped performance year episode spending at the MS–DRG/HCPCS episode type and region level divided by the capped average baseline episode spending in the most recent baseline year dollars at the MS–DRG/HCPCS episode type and region level (that is, national mean benchmark price).

The reconciliation (final) target price will be calculated as the product of the capped mean baseline episode spending in the most recent baseline year dollars, the discount factor, the risk adjustment multiplier using the performance year case-mix, the capped final normalization factor, and the capped retrospective trend factor.

TEAM participants will have the opportunity to achieve a reconciliation payment amount, after accounting for quality performance, if their performance year spending is below the reconciliation target price, or they may owe a repayment amount if their spending is above the reconciliation target price.

(2) Ambulatory Payment Classification (APC) and Medicare Severity Diagnosis Related Groups (MS-DRG) Update Factors

(a) Background

TEAM relies on the Medicare Severity Diagnosis Related Group (MS-DRG) and Healthcare Common Procedure Coding System (HCPCS) codes to identify procedures to initiate an anchor hospitalization or anchor procedure. MS-DRG and HCPCS codes, and more specifically the assignment of HCPCS codes to Ambulatory Payment Classifications (APCs), may be modified because of changes in treatment patterns, technology, and any other factors that may change the relative use of hospital and provider resources. Typically, CMS proposes and finalizes coding changes, as applicable, through established annual payment rules. MS-DRG changes are generally aligned with the fiscal year (FY) in the IPPS/LTCH proposed and final rules, while HCPCS and APC changes generally align with the calendar year (CY) in the Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) proposed and final rules.

Because TEAM uses 3 years of rolling baseline episode spending, with 2 additional historical trend years, to construct target prices for a given performance year, changes in the MS-DRG or HCPCS-APC mappings and weights after the baseline period and either prior to or during the performance year may result in target prices that do not appropriately reflect episode spending in the performance year. Additionally, any new code established prior to or during the performance year that did not exist in the baseline period would not have a target price. In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536), we finalized the definition of a scaling factor at § 512.505 and methodology at § 512.540(a)(2)(i) through (iii) to account for changes to MS-DRGs and HCPCS between the baseline period and the performance year using a three-step mapping and scaling approach. The scaling factor, calculated as the ratio of MS-DRG or APC weight in the performance year to that in the baseline year, accounts for relative weight changes for MS-DRGs in the inpatient setting and APCs for HCPCS in the outpatient setting. However, this approach does not address changes that may arise after preliminary target prices are released to TEAM participants.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), we established that preliminary target prices would be constructed only once per performance

year and shared with TEAM participants prior to each performance year, which covers a calendar year timeframe. Therefore, due to the availability of data and timing of when target prices are released to TEAM participants, target prices are constructed using the previous calendar year HCPCS-APC mappings and weights (that is, the year prior to the performance year) and only the first three quarters of the current fiscal year's MS-DRG definitions and weights. TEAM target prices do not account for any MS-DRG definition or weight changes that are implemented in the last quarter of the performance year because fiscal years span October 1 to September 30. For example, performance year 1 (January 1, 2026-December 31, 2026) preliminary target prices are constructed using calendar year 2025 (January 1, 2025-December 31, 2025) HCPCS-APC mappings and weights and fiscal year 2026 (October 1, 2025-September 30, 2026) MS-DRG definitions and weights. HCPCS-APC mappings and weight changes in the CY OPPS/ASC and MS-DRG definition or weight changes in the FY IPPS/LTCH final rules would alter observed and scaled spending in the baseline period. Further, MS-DRG definition or weight changes may shift which code would initiate an anchor hospitalization and subsequently change the composition of inpatient episodes. As a result, benchmark and target prices would not reflect changes between calendar years (for instance, if HCPCS codes are reassigned to different APC weights during a performance year) or between fiscal years (for instance, MS-DRG definition changes between the first and second fiscal years of a performance year). At reconciliation, these changes may not be sufficiently accounted for by the retrospective trend factor which is capped at  $\pm 3$  percent. Additionally, there may not be benchmark prices or other target price components available for episodes with anchor hospitalization end dates in the second fiscal year. To avoid these inconsistencies we propose application of the following APC and MS-DRG update factors in final target price calculations beginning in performance year 1, to ensure the final target price and reconciliation amounts align with payment rates and weights that are applied during each performance year.

(b) APC Update Factor

We propose to update the Definitions at § 512.505 and the pricing methodology at § 512.540(b)(7) to add an APC update factor to the calculation of the prospective trend factor and at § 512.545(f)(1) to the retrospective trend

factor. We propose to define the APC update factor at § 512.505 as the component applied to the prospective trend factor to ensure that the APC weights corresponding to the performance year are incorporated into the final target price calculations. The APC update factor, as set forth in § 512.540(b)(7), would be calculated at the MS-DRG/HCPCS episode type and region level as the ratio of the benchmark prices calculated with APC weights corresponding to the calendar year of the performance year (CY 2026 for performance year 1) to the preliminary benchmark prices calculated with the APC weights corresponding to the calendar year prior to the performance year (CY 2025 for performance year 1). The APC update factor would be calculated after the CY OPPS/ASC final rule is published each year and would be shared with TEAM participants to ensure that all information that is used to calculate final target prices is available. The APC update factor would be applied as a multiplier to the prospective trend factor, creating an updated prospective trend factor, which will be applied during final target price calculations. Specifically, we propose to update § 512.545(f)(1) such that the retrospective trend factor is capped relative to the updated prospective trend factor to ensure that final target prices are aligned with performance year payment rates and weights.

We believe this would be a straightforward approach to account for calendar year changes in APC weights by directly applying the corresponding changes to the prospective trend factor, without creating and distributing multiple preliminary target prices. For example, TEAM participants would only need to multiply the APC update factor to the prospective trend factor as compared to receiving a new preliminary target price with other updated pricing components. We note that if the APC relative weights decrease between calendar years, the application of the APC update factor may result in a decrease in benchmark prices. Additionally, risk adjustment coefficients are not updated and may not reflect changes between calendar years. Internal analysis assessed the impact of using outdated APC weights on TEAM benchmark prices, comparing the average scaled and winsorized spending in the most recent baseline year at the MS-DRG/HCPCS episode type and region level using CY 2025 and CY 2026 APC weights. Findings from this internal analysis indicate that episodes with APC assignment changes

between calendar years 2025 and 2026 had significant percent differences in APC weights between years (49 percent). Additionally, the percent differences in average scaled and winsorized spending for TEAM initiating episodes with changed APC assignments between calendar years 2025 and 2026 were large, ranging from 33 percent to 40 percent, and the percent difference between baseline benchmark prices ranged from 2 percent to 8 percent.

Though we anticipate only minor adjustments to APC weights during the calendar year, internal analyses indicate that benchmark prices and therefore the final target price calculations at reconciliation would not account for code reassignments that significantly change relative APC weights. We considered but will not propose applying the APC update factor beginning in performance year 2. As detailed below, APC update factors would be shared in advance of final target price calculations and would improve target price accuracy, aligning reconciliation amounts with payment rates and weights applied during the performance year. Given this, we propose adjusting the prospective trend factor methodology at § 512.540(b)(7) and the retrospective trend factor methodology at § 512.545(f)(1) to account for changes in relative APC weights between calendar years in the TEAM performance year.

#### (c) MS-DRG Update Factor

To account for changes in MS-DRG mapping and weights between the first and second fiscal years in a TEAM performance year, we propose updates to the Definitions at § 512.505 and the pricing methodology at § 512.540, § 512.545, and § 512.550 to adjust the target price and reconciliation amount accordingly. Specifically, we propose

updating methodology at § 512.540(b)(7) to add a MS-DRG update factor to the calculation of the prospective trend factor for episodes with anchor end dates in the fourth quarter of the performance year. We propose to define the MS-DRG update factor at § 512.505 as the component applied to the prospective trend factor for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of the performance year to account for changes in MS-DRG definitions and weights between the first and second fiscal years in the performance year. The MS-DRG update factor would be calculated at the MS-DRG/HCPCS episode type and region level as the ratio of benchmark prices calculated with the second fiscal year inputs (FY 27 MS-DRG definitions and weights for performance year 1) to preliminary benchmark prices calculated with the first fiscal year inputs (FY 26 MS-DRG definitions and weights for performance year 1). The MS-DRG update factor would be calculated after the FY IPPS/LTCH final rule is published each year and would be shared with TEAM participants as a multiplier to the prospective trend factor to ensure that all information that is used to calculate final target prices is available.

When TEAM initiating MS-DRGs change between the first and second fiscal years in a performance year, the reconciliation target price for episodes with anchor end dates in the fourth quarter of the performance year will be calculated using MS-DRG mappings and weights from both fiscal years. As proposed at § 512.550(c), initiating MS-DRGs with anchor end dates in the second fiscal year of a performance year would be mapped and assigned a first fiscal year MS-DRG. We propose updating methodology at § 512.545 to specify the fiscal year MS-DRG(s) of

each reconciliation target price component for episodes with anchor end dates in the fourth quarter of the performance year. Components derived from baseline data, such as the benchmark price and the risk adjustment coefficients, would be calculated using MS-DRG mappings and weights from the assigned first fiscal year in a performance year (as described in § 512.545(a) through (d)). The final normalization factor, described at § 512.545(e) would be calculated specific to the assigned first and second fiscal year MS-DRG and region combination, and cannot exceed  $\pm 5$  percent of the prospective normalization factor, as specified at § 512.540(b)(6), for the assigned first FY MS-DRG. For instance, if two TEAM initiating MS-DRGs are mapped to one MS-DRG in the second fiscal year, the normalization factor will be calculated using the benchmark price and risk adjustment coefficients of the assigned first fiscal year MS-DRG applied to the realized case mix of the second fiscal year MS-DRG. The retrospective trend factor described at § 512.545(f) would be calculated with performance year spending specific to the second fiscal year MS-DRG mapping combination, and cannot exceed  $\pm 3$  percent of the updated prospective trend factor. The updated prospective trend factor would be the product of the prospective trend factor and the corresponding APC update factor and MS-DRG update factor. We propose at § 512.505 to define the updated prospective trend factor as the multiplier incorporated into the preliminary target price to estimate changes in spending patterns between the baseline period and the corresponding calendar year and fiscal year in the performance year. See Table X.A-05 for summary of target price components and applicable fiscal year MS-DRGs.

**TABLE X.A.-05: SUMMARY OF APPLICABLE FISCAL YEAR MS-DRG FOR EACH TARGET PRICE COMPONENT IN A PERFORMANCE YEAR**

| Episodes with Anchor End Dates in: | Benchmark Price | Risk Adjuster Coefficients | Risk Adjuster Multiplier | Prospective Normalization Factor | Final Normalization Factor | Prospective Trend Factor | Retrospective Trend Factor |
|------------------------------------|-----------------|----------------------------|--------------------------|----------------------------------|----------------------------|--------------------------|----------------------------|
| Quarters 1-3                       | FY 1            | FY1                        | FY1                      | FY1                              | FY1                        | FY1 *                    | FY1                        |
| Quarter 4                          | FY1             | FY1                        | PY (FY1; FY2)***         | FY1                              | PY (FY1; FY2)***           | FY1 **                   | PY (FY1; FY2)***           |

\* APC-UF as described previously would be applied to the prospective trend factor to generate the updated prospective trend factor in the calculation of target prices.

\*\* APC-UF and DRG-UF as described previously would be applied to the prospective trend factor to generate the updated prospective trend factor in the calculation of target prices.

\*\*\* Refers to the assigned first and second fiscal year MS-DRG mapping combinations as proposed at § 512.550(c)

Further, for performance years in which diagnosis or procedure codes are mapped to different TEAM initiating

MS-DRGs between the first and second fiscal years, we propose updating methodology at § 512.550(c) to add a

step to assign a first fiscal year MS-DRG to episodes with anchor end dates in the fourth quarter. Based on logic described

in the IPPS/LTCH final rules, CMS would identify and map diagnosis and procedure codes from TEAM initiating MS-DRGs in the second fiscal year MS-DRGs to the first fiscal year MS-DRGs. Episodes with anchor end dates in the fourth quarter of the performance year based on the second fiscal year MS-DRG would continue to initiate, and the reconciliation target price assigned to the episode would be specific to the assigned first and second fiscal year MS-DRG mapping combination for each hospital. CMS would sum the values for each second FY MS-DRG/HCPCS episode type and, ultimately, across all

MS-DRG/HCPCS episode types to determine the reconciliation amount. As previously noted, some MS-DRG definition changes may result in preliminary benchmark prices and target price components not being available. See Table X.A-06 for a summary of the possible MS-DRG mapping scenarios between the first and second fiscal year of a TEAM performance year. For example, a non-TEAM MS-DRG, meaning a MS-DRG that does not initiate a TEAM anchor hospitalization, in the first fiscal year is mapped to a TEAM MS-DRG, meaning a MS-DRG that initiates a TEAM anchor hospitalization, in the second fiscal year

of a performance year (scenario 4). In this situation, we would not be able to produce a final target price for the episode, as preliminary benchmark prices and target price components would not be available for the non-TEAM MS-DRG based on the first fiscal year inputs. Therefore, we propose that TEAM participants would not be accountable for episodes with anchor end dates in the fourth quarter of the performance year that are initiated by anchor hospitalizations that would have been assigned a non-TEAM MS-DRGs in the first three quarters of the performance year.

TABLE X.A.-06: SUMMARY OF MS-DRG MAPPING SCENARIOS BETWEEN FISCAL YEARS OF A PERFORMANCE YEAR

| Scenario                                                                     | Fiscal Year 1 MS-DRG | Fiscal Year 2 MS-DRG | TEAM Participant Episode Accountability under the Proposed Approach |
|------------------------------------------------------------------------------|----------------------|----------------------|---------------------------------------------------------------------|
| 1. No MS-DRG mapping changes                                                 | TEAM MS-DRG AAA      | TEAM MS-DRG AAA      | Accountable for episodes in both fiscal years.                      |
| 2. Mapping changes result in a TEAM MS-DRG mapped to a different TEAM MS-DRG | TEAM MS-DRG AAA      | TEAM MS-DRG BBB      | Accountable for episodes in both fiscal years                       |
| 3. Mapping changes result in a TEAM MS-DRG mapped to a Non-TEAM MS-DRG       | TEAM MS-DRG AAA      | Non-TEAM MS-DRG CCC  | Accountable for episodes in fiscal year 1 but not fiscal year 2     |
| 4. Mapping changes result in a Non-TEAM MS-DRG mapped to a TEAM MS-DRG       | Non-TEAM MS-DRG CCC  | TEAM MS-DRG BBB      | Not accountable for episodes in either fiscal year.                 |

We believe adding the MS-DRG update factor to the calculation of prospective trend factors for episodes with anchor end dates in the fourth quarter of the performance year is an effective way to account for fiscal year changes in MS-DRG definitions and weights without reissuing preliminary target prices and reduces TEAM participant burden by not having to manage multiple preliminary target prices within a given performance year. We acknowledge that, depending on the magnitude of changes between the fiscal years in the performance year, some target prices may lack precision or may not be available. Specifically, the risk adjustment coefficients are not updated

and will be more reflective of the first fiscal year case mix. Internal analysis used fiscal years 2024 and 2025 inputs to assess the impact of MS-DRG mapping and weight changes between fiscal years on TEAM benchmark prices. This assessment demonstrated that conducting reconciliation calculations using target prices solely based on FY 2024 inputs, without accounting for FY 2025 MS-DRG mappings and weight changes, may penalize participants. Specifically, five spinal fusion MS-DRGs were deleted in FY 2024 and mapped to 10 new spinal fusion MS-DRGs in FY 2025. As a result, 72 percent of final TEAM spinal fusion episodes were without available FY

2024 benchmark prices, and differences in scaled inpatient stay costs ranged from – 56 percent to 71 percent. As previously noted, the APC and MS-DRG update factors would be calculated after the CY OPPI/ASC and the FY IPPS/LTCH final rules are published and would be shared with TEAM participants to ensure that all information that is used to calculate final target prices is available. Table X.A-07 provides an example operational timeline of APC and MS-DRG update factor availability. We note that the operational timeline is subject to change contingent on finalization and publication of the CY OPPI/ASC and FY IPPS/LTCH rules.

TABLE X.A.-07: EXAMPLE OPERATIONAL TIMELINE OF APC UPDATE FACTOR AND MS-DRG UPDATE FACTOR AVAILABILITY

| Performance Year | Preliminary Target Prices       | APC Update Factor               | MS-DRG Update Factor            |
|------------------|---------------------------------|---------------------------------|---------------------------------|
| 1                | 4 <sup>th</sup> quarter of 2025 | 4 <sup>th</sup> quarter of 2026 | 4 <sup>th</sup> quarter of 2026 |
| 2                | 4 <sup>th</sup> quarter of 2026 | 1 <sup>st</sup> quarter of 2027 | 4 <sup>th</sup> quarter of 2027 |
| 3                | 4 <sup>th</sup> quarter of 2027 | 1 <sup>st</sup> quarter of 2028 | 4 <sup>th</sup> quarter of 2028 |
| 4                | 4 <sup>th</sup> quarter of 2028 | 1 <sup>st</sup> quarter of 2029 | 4 <sup>th</sup> quarter of 2029 |
| 5                | 4 <sup>th</sup> quarter of 2029 | 1 <sup>st</sup> quarter of 2030 | 4 <sup>th</sup> quarter of 2030 |

We considered but are not proposing to update and deliver preliminary target

prices to TEAM participants for each calendar and fiscal year final rule. We

believe managing three different preliminary target prices in a given

performance year will increase participant burden and pricing methodology complexity. We also considered, but are not proposing, to backwards map and descale spending for episodes with anchor end dates in the fourth quarter of the performance year. A descaling factor, the ratio of MS-DRG relative weight in the first fiscal year to the MS-DRG relative weight in the second fiscal year, would be applied to episode spending. The descaled episode costs would be applied to the numerator of the retrospective trend factor as well as directly to the final target price through a factor, which would be calculated as the difference between the average episode cost and the average descaled episode cost, divided by the preliminary target price plus one. Episodes with anchor end dates in the fourth quarter of the performance year would be triggered based on the mapped first fiscal year MS-DRG and reconciled using original episode costs before descaling. Although this approach could improve target price accuracy, we believe it would introduce additional complexity, increasing the risk of confusion and challenges in implementation. We considered but will not propose applying the update factors beginning in performance year 2. We believe this would negatively impact participants in performance year 1, resulting in misalignment between target prices, reconciliation amounts, and payment rates and weights applied during the performance year. However, we seek comment on this alternative considered. Lastly, we also considered but are not proposing removing the  $\pm 3$  percent capping of the retrospective trend factor adjustment. Applying a full retrospective trend factor to reconciliation target prices, rather than capping at  $\pm 3$  percent would account for actual performance year spending and would incorporate APC or MS-DRG mapping and weight changes not captured in preliminary target prices. However, we recognize that removing the  $\pm 3$  percent cap may introduce target price instability making it more difficult for TEAM participants to predict reconciliation target prices and assess spending performance in the model.

We seek comment on our proposal at § 512.505 to add definitions of the APC update factor, MS-DRG update factor, and updated prospective trend factor. We also seek comment on our proposal at § 512.540(b)(7) to add APC and MS-DRG update factors in the calculation of the prospective trend factor to account for changes in HCPCS-APC and MS-DRG mappings and weights during a

TEAM performance year. We also seek comment on our proposals for performance years in which diagnosis or procedure codes are mapped to different TEAM triggering MS-DRGs between the first and second fiscal years. At § 512.545 to specify the FY MS-DRG(s) that each reconciliation target price component reflects for episodes with anchor end dates in the fourth quarter of the performance year. At § 512.550(c) to add a step to assign a first fiscal year MS-DRG to performance year episodes with anchor end dates in the fourth quarter and modify the calculations to the assigned first and second fiscal year MS-DRG/HCPCS episode type.

### (3) Prospective Normalization Factor Construction

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, a normalization factor was included in the calculation of preliminary and reconciliation target prices to ensure that the average benchmark price after risk adjustment does not exceed the average benchmark price prior to risk adjustment. The FY26 IPPS/LTCH PPS final rule (90 FR 36536) revised the language at § 512.505 to clarify that the prospective normalization factor will be calculated using the benchmark prices rather than using preliminary target prices. Additionally, the FY26 IPPS/LTCH PPS final rule modified §§ 512.540(b)(6) and 512.545(e)(1)(i) to calculate the prospective and final normalization factors at the MS-DRG/HCPCS episode type and region level rather than at national level.

For each MS-DRG/HCPCS episode type and region combination, the normalization factor is calculated as the average benchmark price divided by the average risk-adjusted benchmark price. The risk-adjusted benchmark price is the product of the benchmark price and a risk adjustment multiplier, which accounts for variation in spending due to hospital and beneficiary characteristics. The risk adjustment multiplier, as defined in current policy at § 512.540(b)(6)(i), is calculated by applying risk adjustment coefficients to the most recent baseline year episodes. Since the baseline period, as defined in § 512.505 and further addressed in § 512.540(b)(2), is a rolling three-year period, the most recent baseline year for a given performance year would always be baseline year 3. The construction of the normalization factor relying on the most recent baseline year was designed to maintain simplicity while using the most recent data available. However, we have concerns that only using the most recent baseline year may not accurately

reflect all the episodes used to calculate the benchmark price. Nor does using only the most recent baseline year consistently recenter the risk adjusted benchmark prices back to the average of the total non-risk adjusted benchmark price.

To improve predictive accuracy, better represent all episodes used in benchmark price construction, and recenter the risk adjusted benchmark price to the average of the total non-risk adjusted benchmark price, we propose that starting with performance year 2 to update the definition at § 512.540(b)(6) to calculate the prospective normalization factor at the MS-DRG/HCPCS episode type and region level based on the applicable episodes in the baseline period. We propose to update § 512.540(b)(6)(i) to apply the risk adjustment coefficients to all applicable baseline year episodes, rather than restricting application to the most recent baseline year episodes, in the calculation of the risk adjustment multiplier. This should improve the accuracy of the multiplier and help to smooth short-term fluctuations, if any, in the most recent baseline year. An internal analysis compared the observed and expected average hospital-level spending for each MS-DRG/HCPCS episode type and region using clinical episodes with start dates on or after January 1, 2022, and anchor end dates on or before December 31, 2024. Findings demonstrated that the multipliers and normalization factors constructed with all the baseline episodes improved predictive accuracy compared to those constructed using only the most recent baseline year episodes. We note the difference between the MS-DRG/HCPCS episode type and region-level normalization factors calculated using only the most recent baseline year episodes and the normalization factors calculated using all baseline year episodes ranged from -0.03 to 0.02 (-3.46 percent to 2.56 percent). While this difference was small, we believe using all baseline episodes to construct the normalization factor is a more sound mathematical approach and will recenter average expected spending around average observed spending.

We considered but are not proposing to calculate the normalization factor using an additional two years of data prior to the baseline period, similar to the trend factor construction. However, this would not recenter the risk adjusted benchmark prices and would not improve predictive accuracy.

We seek comment on our proposal at § 512.540(b)(6) and (b)(6)(i) to calculate the risk adjustment multiplier and

normalization factor using the baseline period clinical episodes starting with performance year 2.

#### d. Ambulatory Surgical Center (ASC) Episode Request for Information

CMS is exploring Ambulatory Surgical Center (ASC) participation in the Transforming Episode Accountability Model (TEAM), beginning as early as CY2028 (that is, Performance Year 3). We acknowledge previously soliciting public comment on inclusion of ASCs in Lower Extremity Joint Replacement (LEJR) focused models (85 FR 10537) in the Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing proposed rule. Certain orthopedic procedures, such as total knee arthroplasty (TKA), were covered by Medicare in the ASC setting beginning January 1, 2020 (84 FR 61253). However, given its recent addition to the ASC covered procedure list, there was not a significant volume of TKA procedures performed in the ASC setting at the time and the CJR model did not add procedures in ASC settings to its episodes. We recognize that since that RFI the health care landscape has changed and more procedures, including certain procedures that initiate episodes in TEAM, are being performed more regularly in the ASC setting. Therefore, we recognize the importance of soliciting additional public feedback on inclusion of ASC episodes in TEAM.

Beyond systemic differences in payment policy and beneficiary populations, ASCs do not have the same relationship to hospitals as inpatient (IP) and outpatient (OP) hospital departments. Thus, procedures in ASCs would need to be incorporated into TEAM differently than procedures performed in the OP setting. We also recognize that testing TEAM in the ASC setting will likely impact the evaluation of TEAM by changing the health care landscape within which hospital participation in TEAM is evaluated. These impacts may occur in various ways including possible changes in the patient mix and volume in various settings for covered procedures. This request for information (RFI) seeks public input on model structure, participant roles and financial accountability, episode and target price construction, and quality measurement. Through this RFI, we intend to gather public input on the parameters under which ASCs could be incorporated into TEAM, including the degree to which the addition of ASCs would necessitate a separate model test. Any future

incorporation of ASCs in TEAM, whether as an additional participant population under the current model test or as a distinct model test with the TEAM episode structure applied, would be pursued through notice-and-comment rulemaking under the authority of section 1115A of the Act. Feedback on this RFI will inform potential future rulemaking to incorporate ASCs in TEAM in a manner that promotes both efficient and high-quality care, safeguards appropriate patient selection, and aligns incentives across care settings.

#### • Participation and Financial Accountability.

++ What operational challenges would ASCs face participating in an episode-based payment model such as TEAM? Are there any unique challenges to treating patients in an ASC compared to IP/OP hospital settings? How might these challenges impact model participation?

++ What steps could CMS take to support ASC readiness to participate in episode-based payment models such as TEAM?

++ What programmatic waivers may be necessary to ensure ASCs have successful participation in TEAM?

++ What entity should be held financially accountable for episodes initiated at ASCs?

++ How should CMS account for financial and ownership relationships between hospitals and ASCs or both?

++ What barriers are there to partnerships between hospitals and ASCs that are not owned by hospitals?

++ What opportunities, if any, exist for ASCs to achieve efficiency gains under TEAM? What model features could support or enhance these opportunities?

#### • Episode Construction.

++ What additional surgical episode types should CMS consider if TEAM is modified to include the ASC setting?

#### • Risk Adjustment and Target Pricing.

++ If CMS incorporates ASCs into multi-setting episode types, how can CMS adapt the beneficiary-level risk adjustment methodology to ensure appropriate site-of-service decisions?

++ Could including ASCs in TEAM create barriers to care for any Medicare beneficiaries? What could CMS do to mitigate this?

#### • Model Overlap.

++ How should CMS handle TEAM ASC episode overlap with other value-based care initiatives or payment models focused on the same procedures at either ASCs or hospitals?

#### • Quality Measures.

++ What quality measures would reasonably capture performance and outcomes of TEAM ASC episodes?

++ On what quality metrics can ASCs and hospital outpatient departments be fairly compared?

++ What opportunities, if any, exist for quality improvement at ASCs for procedures included in (or suggested for inclusion in) TEAM?

#### e. Hospital with Physician Ownership Request for Information

A hospital with physician ownership (POH) is any hospital in which a physician, or an immediate family member of a physician, has an ownership or investment interest in the hospital. Ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in the hospital.<sup>451</sup> It is estimated that more than 250 acute care hospitals are owned, in part or fully, by physicians.<sup>452</sup>

Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also known as the physician self-referral law (and commonly referred to as the “Stark” law):

- Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and

- Prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payor) for any improperly referred designated health services.

A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (HHS) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers (the “rural provider exception”). To use the rural provider exception, an entity must furnish substantially all of the

<sup>451</sup> 42 CFR 411.351 and 411.254(b).

<sup>452</sup> Blumenthal et al. Access, quality, and costs of care at physician owned hospitals in the United States: observational study. *BMJ* 2015; 351. <https://www.bmj.com/content/351/bmj.h4466>.



designated health services that it furnishes to residents of a rural area (as defined in section 1886(d)(2) of the Act). To satisfy the requirements of the rural provider exception, the designated health services must be furnished in a rural area and, in the case where the entity is a hospital, the hospital must meet the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. Section 1877(d)(3) of the Act provides an exception for ownership or investment interests in a hospital located outside of Puerto Rico (the “whole hospital exception”). To satisfy the requirements of the whole hospital exception, the referring physician must be authorized to perform services at the hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the hospital), and the hospital must meet the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. These exceptions are codified in our regulations at § 411.356(c)(1) and (3), respectively.

Section 6001(a) of the Affordable Care Act effectively eliminated the exceptions for physician ownership or investment in hospitals, although hospitals with physician ownership or investment and a Medicare provider agreement on December 31, 2010, are grandfathered and able to continue using the rural provider exception, if applicable, and the whole hospital exception.

Section 6001(a)(3) of the Affordable Care Act amended the rural provider exception and the whole hospital exception to provide that a hospital with physician ownership or investment may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a Medicare provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement). However, the Secretary may grant an exception from the prohibition on facility expansion.

To avoid the underlying concerns of the physician self-referral law, including but not limited to overutilization, patient steering, cherry-picking, and lemon-dropping, current law limits expansion of POHs. However, there is some evidence that suggests that POHs may help control costs, maintain or improve patient outcomes, and prevent hospital

consolidation.<sup>453 454 455 456</sup> The CMS Innovation Center is considering initiating a voluntary opt-in period to allow POHs located in core-based statistical areas (CBSAs) not selected for Transforming Episode Accountability Model (TEAM) inclusion to participate in the Model. TEAM aims to improve patient experience, incentivize hospitals to implement care redesign, and promote collaboration with Accountable Care Organizations and primary care providers for certain surgical procedures. TEAM has approximately 15 POHs mandated to participate in the model and does not include any POH-specific waivers.

Designed as a mandatory model, voluntary participation in TEAM has cost and evaluation implications on the model. We noted concerns with voluntary participation in TEAM when the model was initially proposed (89 FR 36390) and believe that guardrails must be in place if voluntary participation were permitted in the model. This is because self-selection of voluntary participants may result in net costs to Medicare or reduce anticipated savings. Further, the voluntary participation of POHs in the TEAM model risks the integrity of the evaluation design and may lead to biased findings undermining the model test. While certain hospitals were permitted to voluntarily opt into TEAM (42 CFR 512.510), they could only be located in strata 17 or 18 (42 CFR 512.515), and we did inhibit their ability to voluntarily exit the model and required participation in all episode categories to curtail self-selection and participation attrition concerns. We anticipate that any potential future voluntary participation opportunities would include similar parameters to ensure model integrity and minimize losses to Medicare.

We request feedback on the following questions:

<sup>453</sup> Ahn, J., Blumenthal, S., & Derman, P. B. (2019). Physician-owned hospitals in orthopedic and spine surgery. *Annals of translational medicine*, 7(Suppl 5), S162. <https://doi.org/10.21037/atm.2019.06.49>.

<sup>454</sup> Courtney, P. M., Darrih, B., Bohl, D. D., Frisch, N. B., & Della Valle, C. J. (2017). Reconsidering the Affordable Care Act's restrictions on Physician-Owned hospitals. *Journal of Bone and Joint Surgery*, 99(22), 1888–1894. <https://doi.org/10.2106/jbjs.17.00203>.

<sup>455</sup> Wilensky, G., & Miller, B. (2020). Time to consider a new look at Physician-Owned hospitals to increase competition in health care? *JAMA*, 323(19), 1884. <https://doi.org/10.1001/jama.2020.6106>.

<sup>456</sup> Reversing hospital consolidation: The promise of Physician-Owned Hospitals. (2021). [Dataset]. In Forefront Group. <https://doi.org/10.1377/forefront.20210408.980640>.

- Should CMS allow a voluntary opt-in period to include POHs in TEAM; why or why not? Should the option to participate in TEAM be limited to those POHs that are grandfathered under the Affordable Care Act to use the rural provider or whole hospital exception to the physician self-referral law?

- Should POHs that wish to voluntarily opt into TEAM be required to meet the geographic eligibility criteria described previously and in 42 CFR 512.515 and be subject to participation requirements described in 42 CFR 512.510? What inclusion criteria, if any, should be added for POHs opting to participate in TEAM?

- What programmatic waivers may be necessary to ensure POHs have successful participation in TEAM (for example, restrictions on expansion of facility capacity, service limitations, etc.)? Provide justification for any waiver that you believe may be necessary. Please explain how the waiver will not undermine the TEAM model by allowing Medicare payment for services furnished by POHs where such payments are not currently allowed because the POHs are not grandfathered in to use the rural provider or whole hospital exception to the physician self-referral law.

- Waivers of law, if provided and necessary to test a model, are temporary and generally end when the model expires or the participant's agreement is terminated. How will POHs continue any successful actions taken under TEAM once they must comply with all applicable statutes and regulations, including the physician self-referral law?

- How can CMS ensure that, upon the termination of TEAM and any associated waivers specific to POHs, if granted, that POHs remain compliant with existing mandates? For example, if TEAM waives Section 6001(a)(3) of the Affordable Care Act to allow a POH to expand beyond its baseline number of operating rooms, procedure rooms, and beds (as defined at 42 CFR 411.363(a)) without requesting an expansion from the Secretary as required at 42 CFR 411.362(b)(2), how can CMS ensure that the POH reduces its facility capacity to its baseline number of operating rooms, procedure rooms, and beds?

- What additional program integrity requirements should CMS consider to avoid beneficiary steering, cherry-picking, and lemon-dropping and ensure beneficiary choice is not compromised if waivers are offered to POHs?

- Should any episode categories be excluded from episode initiation, or should any items and services be



excluded from target prices for POHs in TEAM? If so, include evidence to support this exclusion.

- What episode categories, beyond the episode categories currently tested in TEAM should CMS consider testing for POHs?

*B. Proposed Revision to Provider-Based Location Criteria Regulations Applicable to Off-Campus Facilities or Organizations (§ 413.65)*

1. Background

The Medicare law lists the types of facilities that are regarded as providers of services but does not use or define the term “provider-based” (section 1861(u) of the Act). However, since the beginning of the Medicare program, some providers, referred to as *main providers*, have functioned as a single entity while owning and operating multiple subordinate facilities that were treated as part of the main provider for Medicare purposes (as related to, for instance, payment; certification; coverage; and/or billing). With this, such provider-based facilities might enjoy a number of advantages, including most notably, increased payments from Medicare. Therefore, we have maintained that having clear criteria for acquiring provider-based status, as opposed to operating as a freestanding facility, is important because failure to properly distinguish between the two risks overpayment to the latter, which can result in increased beneficiary coinsurance liability, with no commensurate benefit to the Medicare program or its beneficiaries.

Program Memorandum A-967, published on August 27, 1996, provided instructions for specific entity types from previously published documents consolidated into a general instruction for the designation of provider-based status for all facilities or organizations. That Program Memorandum was subsequently reissued, without substantive change, as Program Memoranda A-98-15 and A99-24 and, in October 1999, was manualized by the Provider Reimbursement Manual, Part I, Transmittal 411 (adding new section 2446), and the State Operations Manual, Transmittal 11 (replacing previous section 2003 and adding new section 2004). The Medicare rules regarding provider-based status of facilities and organizations are set forth at 42 CFR 413.65 and have been revised and updated on numerous occasions since initial issuance on April 7, 2000 (65 FR 18504). We note that implementation of the April 7, 2000 regulations was delayed for many providers by Public Law 106-554 in the Medicare,

Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which further amended the criteria for determining provider-based status, as implemented in a final rule published in the **Federal Register** on November 30, 2001 (66 FR 59909).

Since the initial creation and implementation of the provider-based rules, CMS included requirements that the facility or organization seeking provider-based status and the main provider either be located on the same “campus,” as defined in regulations,<sup>457</sup> or, amongst other criteria, demonstrate they serve the same patient population. In the initial versions of the provider-based rules, the requirements regarding servicing the same patient population included a requirement that the facility or organization seeking provider-based status be in the “immediate vicinity” of the main provider’s campus. The precise distance for an “immediate vicinity” determination was not defined in rulemaking, though the limit was generally understood to not exceed 35 road miles from the main facility, consistent with prior guidance. In response to a commenter in the final rule with comment period published in the **Federal Register** on April 7, 2000 (65 FR 18516), CMS concurred that establishing more precise criteria was required and finalized alternative methods to determine whether a provider-based facility or organization could demonstrate that it serves the same patient population as the main provider, even if it did not meet the “immediate vicinity” criterion. As revised, this “same patient population” test required hospitals to annually demonstrate a geographic overlap in service area through comparisons of patients’ home zip code data from the main provider and the facility or organization seeking provider-based status.

Section 404(b) of BIPA further amended the immediate vicinity criterion by stating that the facility or organization must be located within a 35-mile radius of the potential main provider. The legislation also maintained the criteria previously finalized by CMS to demonstrate that a facility or organization serves the “same patient population” as the potential main provider (the “75 percent” tests). And to encourage delivery of care to uninsured, low-income individuals, BIPA added alternative qualification criteria for certain hospitals with a disproportionate share adjustment greater than 11.75 percent.

<sup>457</sup> See 42 CFR 413.65(a)(2).

In the FY 2001 IPPS/LTCH PPS final rule (65 FR 18517 through 18518), commenters requested that the requirement to serve the same patient population be modified to exclude off-campus inpatient facilities of hospitals because these facilities provide similar types of service as the main provider but serve patient populations from different geographic areas. We responded by stating that CMS recognizes there may be some cases in which a main hospital and another facility or organization seeking provider-based status may meet most or all other determining criteria in the regulations yet not qualify under the same patient population tests. We disagreed that this result should lead us to abandon the same patient population test, however, and pushed back on the commenter’s assumption that because the program memorandum and proposed rule were issued in response to situations primarily involving outpatient facilities, they can apply only to such facilities. In that rule, we expressed specific concerns regarding payment implications for certain potential arrangements that we believed warranted application of the provider-based rules to both outpatient and inpatient locations. Specifically, we stated that the establishment of off-campus facilities excluded from the inpatient PPS could lead to payment abuses, such as circumvention of certain payment caps. We further addressed more general requests to exempt off-campus inpatient facilities from provider-based rules in the FY 2003 IPPS/LTCH PPS final rule (67 FR 50081 through 50082), reaffirming our position that provider-based rules should apply to both inpatient and outpatient facilities and organizations.

2. Proposed Revision to the “Same Patient Population” Location Criteria

To satisfy the location criterion set forth at § 413.65(e)(3)(iii), the regulation requires the facility or organization demonstrate that it serves the “same patient population” as the main provider by submitting records showing that, during the immediately preceding 12-month period, and for each subsequent 12-month period, that either: at least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider (§ 413.65(e)(3)(iii)(A)); or at least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (§ 413.65(e)(3)(iii)(B)). The provision at § 413.65(e)(3)(iv) provides a

temporary test for newly established facilities that would not yet have 12 months of data to evaluate. We continue to believe that hospitals operating off-campus inpatient sites, such as a remote location or satellite facility, must meet one of the location requirements set forth in § 413.65(e)(3). However, upon further evaluation, we have concerns that aspects of the 75 percent tests do indeed pose an issue regarding facilities that furnish inpatient services.

Within the text of § 413.65(e)(3)(iii)(B), an example is utilized to illustrate that to meet the requirement a hospital must demonstrate that at least 75 percent of the patients of a rural health clinic (RHC) seeking provider-based status received inpatient hospital services from the main provider hospital. This example describes a *referral* relationship between the main provider and the off-campus facility. That is, in certain geographic areas, where obtaining more acute follow-up care may require longer travel times, this provision provides an exception to a distance-based criterion for establishing the boundaries for a “same patient population” service area. We believe this example was provided to reinforce CMS’ intention that this provision could be applied to exceptionally isolated outpatient facilities where additional services are routinely received by patients at more distant acute care facilities. Distinguishably, however, if a hospital chooses to operate two distinct inpatient locations more than 35 miles apart, we do not believe the hospital should be able to document that they serve the same patient population via the referral-based 75 percent test. Further, for PPS hospitals, inpatient services are generally paid based on the geographic location of the inpatient facility. Obtaining provider-based status for a remote location facility would, therefore, not have significant financial implications. By contrast, however, we are concerned that allowing this referral-based exception for inpatient facilities, certain specialty and PPS-excluded hospitals could obtain significant payment advantages for inpatient services provided at considerable distances from the main provider. We are aware that hospitals may, on occasion, transfer, or schedule additional follow-up for patients between related inpatient facilities. Even so, we believe these cases are likely limited to exceptional circumstances and not adequately demonstrative of whether one facility provides services to the same patient population as another.

For these reasons, we are proposing to limit the application of § 413.65(e)(3)(iii)(B) to outpatient departments only. When a patient that “required the type of care furnished by the main provider” is referenced, it was contemplated that the encounter(s) at the proposed provider-based location would deliver outpatient services rather than inpatient services. We believe that this proposed revision maintains the original intent of the policy by permitting a proposed provider-based outpatient practice location to exceed the 35-mile radius in circumstances where inpatient services are not readily available in the area. And eliminates the aforementioned potential for arguably unwarranted payment advantages by certain hospitals. Accordingly, we are proposing to revise § 413.65(e)(3)(iii)(B) to specify that at least 75 percent of the patients served by an outpatient facility or organization who required the type of care furnished by the main provider received that care from that provider. An inpatient facility or organization, by contrast, would be excluded from utilizing this test to meet the location requirement altogether. Further, we are proposing the addition of clarifying language at § 413.65(e)(3)(iii)(A) to make explicit that provision may still be utilized by either an inpatient or outpatient facility or organization.

We seek comment on this proposal.

### *C. Proposed Expansion of the Comprehensive Joint Replacement (CJR) Model*

#### 1. Overview of Proposed Expansion of the Comprehensive Care for Joint Replacement (CJR) Model

##### a. Introduction

CJR was a mandatory alternative payment model tested by the Center for Medicare and Medicaid Innovation (Innovation Center) between April 1, 2016, and December 31, 2024 in all eligible acute care hospitals within selected Metropolitan Statistical Areas (MSAs). Based on evaluation results indicating the model successfully reduced spending without reducing quality of care and the Secretary determining that the model has met the requirements for expansion, as described in section X.C.1.c. of this proposed rule, we are proposing to expand CJR to all eligible acute care hospitals nationwide. The proposed CJR model expansion, referred to as the Comprehensive Care for Joint Replacement Expanded (CJR–X) Model, presents an opportunity to further improve the quality of care for lower extremity joint replacements (LEJRs) furnished to Medicare beneficiaries

nationwide by incentivizing hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial hospitalization or procedure through recovery. If finalized, all eligible acute care hospitals would be required to participate in the CJR–X model beginning October 1, 2027.

In order to distinguish our discussion of proposed policies for CJR–X from our discussion of the initial CJR Model test, we will refer to the latter as “the CJR Model”. Additionally, we note that the CJR Model was initially designed to end on December 31, 2020, but was extended with modifications to the methodology, as described in section X.C.1.b. of this proposed rule. As a result, some of the policies we discuss in this proposed rule will have been applicable only prior to the extension while others will have been applicable only during the extension period (for example, the extension period broadened the definition of episodes to include outpatient episodes and modified the target price methodology). To distinguish the timeframe in which these particular policies applied, we will henceforth use the term “original CJR Model” for the former and “CJR Extension” for the latter. For specific policies that were consistent across both the original and extension periods, or discussion of the CJR Model test as a whole, we will continue to use the term “the CJR Model.” To distinguish the performance years in the CJR Model as defined at § 510.2 from our proposed definition of performance years (PYs) in CJR–X at § 512.605, we will refer to the former as “CJR Model PYs.”

##### b. Background

The Innovation Center implemented the CJR Model under the authority of section 1115A of the Act, through notice-and-comment rulemaking. The Innovation Center issued a final rule titled “Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services” (referred to as the “2015 CJR final rule”), which appeared in the November 24, 2015 **Federal Register** (80 FR 73274). The first CJR Model performance period began April 1, 2016. The goal of the CJR Model was to support better and more efficient care for beneficiaries undergoing the most common inpatient surgeries for beneficiaries: hip and knee replacements (also called lower extremity joint replacements or LEJR). Using the randomized selection methodology finalized in the 2015 CJR

final rule, we selected 67 MSAs and initially required the approximately 800 acute care hospitals located in those MSAs to participate in the model through December 31, 2020. The selection of mandatory MSAs was reduced to 34 of the original 67 in later performance years of the model to focus on highest average spending MSAs to allow us to evaluate the effects of the CJR Model across a wide range of providers, including some that might not otherwise participate in the model (82 FR 57073).

The CJR Model tested quality and spending accountability for an episode of care associated with hip and knee replacements to encourage hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial hospitalization through recovery. Specifically, the CJR Model was a retrospective bundled payment model where CMS provided participant hospitals with a target price for each CJR episode type (based on the MS-DRG assigned to the hospitalization and the presence or absence of a hip fracture in the original CJR Model and the MS-DRG or HCPCS code assigned to the hospitalization or procedure in the CJR Extension), prior to the start of each CJR Model PY. All providers and suppliers furnishing LEJR episodes of care to patients throughout the year were paid under existing Medicare payment systems. The target price included a discount that served as Medicare's portion of reduced expenditures from the LEJR episode, and initially incorporated a blend of historical, hospital-specific spending and regional spending for LEJR episodes, with the regional component of the blend increasing over time and eventually being 100 percent regional for PYs 4 through 8. Following the end of a CJR Model PY, actual total spending for a hospital's episodes was compared to the target price for those episodes. Depending on the participant hospital's quality and episode spending performance, the hospital could receive an additional payment from Medicare if spending was less than the target price or be required to repay Medicare for a portion of the episode spending that exceeded the target price.

In the January 2017 final rule (82 FR 180) and the December 2017 final rule (82 FR 57066), CMS implemented revisions to the CJR Model, including creating an Advanced APM track within the model and finalizing technical refinements and clarifications for certain payments, reconciliation and quality provisions. Additionally, in the December 2017 final rule, CMS offered

rural and low-volume hospitals selected for participation in the CJR Model, as well as those hospitals located in 33 of the 67 MSAs, a one-time option to choose whether to continue their participation in the model until the initial CJR Model end date of December 31, 2020. All other participating hospitals in the remaining 34 MSAs continued to be mandatory participants (henceforth referred to as "mandatory hospitals").

While initial evaluation results for the first and second year of the CJR Model indicated that the model was having a positive impact on lowering episode costs when CJR participant hospitals were compared to non-CJR hospitals (with no negative impacts on quality of care), changes in program payment policy and national care delivery patterns had occurred since the CJR Model began.<sup>458 459</sup> Specifically, knee replacements (total knee arthroplasty, or TKA) had been removed from the Inpatient Only (IPO) List as of January 1, 2018. Hip replacements (total hip arthroplasty, or THA) were subsequently removed from the IPO List as of January 1, 2020. These policy changes meant that TKA and THA procedures would be paid by Medicare when performed in the outpatient setting (meaning in a hospital outpatient department, or HOPD). However, the definition of an episode in the original CJR Model included only those TKA and THA procedures performed in the inpatient setting. Additionally, changes in national care delivery patterns meant that hospitals nationwide (including those not participating in the CJR Model) were reducing spending on LEJR episodes, but the model's original prospective target price methodology did not sufficiently account for these nationwide trends. As a result, target prices were artificially inflated, leading to concerns about the ability of the model to demonstrate savings over time.

In order to update the original CJR Model to address those changes to policy and care delivery patterns and improve the model's ability to demonstrate savings, CMS issued a proposed rule titled "Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing" (referred to as the "2020 CJR 3-Year Extension proposed rule"), which appeared in the

February 24, 2020 **Federal Register** (85 FR 10516). This rule proposed to extend the CJR Model for an additional three CJR Model PYs with modifications that included adding outpatient TKAs and THAs to the episode definition, adjusting the target price methodology and risk adjustment, and simplifying the reconciliation process.

Shortly before the 2020 CJR 3-Year Extension proposed rule was published, on January 31, 2020, Secretary of Health and Human Services Alex M. Azar II determined that a public health emergency (PHE) existed and had existed nationwide since January 27, 2020 due to confirmed cases of the 2019 Novel Coronavirus (2019-nCoV, hereafter referred to as "COVID-19").<sup>460</sup> In April 2020, in response to the COVID-19 PHE, CMS issued the April 2020 Interim Final Rule with Comment Period (IFC) (85 FR 19230), which addressed the impact of the COVID-19 PHE on participant hospitals. CMS delayed the proposed extension and modification of the original CJR Model and instead extended CJR Model PY5 through March 31, 2021, to minimize disruption to CJR Model participants as they dealt with the challenges of the COVID-19 PHE. CMS also adjusted the CJR Model's extreme and uncontrollable circumstances policy (originally designed to provide a time-limited period of financial protection to hospitals in the case of natural disasters such as hurricanes, floods, and wildfires) to apply to all CJR episodes during the COVID-19 PHE. This updated policy effectively waived downside risk for all CJR episodes during the COVID-19 PHE.

Subsequently, CMS issued the November 2020 interim final rule with comment period (IFC) (85 FR 71142), which implemented several changes to the CJR Model. Among them, CMS made a technical change to include MS-DRGs 521 and 522 in the CJR episode definition to ensure that the model continued to include the same inpatient LEJR procedures, despite the introduction in FY 2020 of new MS-DRGs to describe those procedures. CMS also finalized a more targeted application of the extreme and uncontrollable circumstances policy to episodes with a COVID-19 diagnosis. This change increased the likelihood of model savings while providing participants with financial protection against COVID-19 episodes after the COVID-19 PHE ended.

<sup>458</sup> Comprehensive Care for Joint Replacement Model—First Annual Report (<https://www.cms.gov/files/document/cjr-firstannrptpdf.pdf>).

<sup>459</sup> Comprehensive Care for Joint Replacement Model—Second Annual Report (<https://www.cms.gov/files/document/cjr-secondannrptpdf.pdf>).

<sup>460</sup> Administration for Strategic Preparedness & Response: Determination That A Public Health Emergency Exists (<https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx>).

Evaluation results from the first four years of the CJR Model indicated that mandatory hospitals generated \$72 million in savings to Medicare while maintaining quality, although the savings were not statistically significant. But in PY 5, reconciliation payments substantially increased, generating \$95.4M in statistically significant Medicare losses, due to adjustments made to the model during the COVID–19 PHE. CMS implemented these temporary adjustments, which effectively waived downside risk for all CJR episodes, in order to minimize any financial burden associated with model participation given the financial challenges and uncertainties hospitals faced early in the COVID–19 PHE. These adjustments resulted in reconciliation payments being triple what they were in previous years, which reversed the savings trajectory and resulted in statistically significant losses to Medicare for mandatory hospitals. The losses in CJR Model PY 5 were large enough to offset total estimated savings prior to the PHE.<sup>461</sup>

In order to return the model to a savings trajectory, CMS published the final rule titled “Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing; Medicare and Medicaid Programs; Policies and Regulatory Revisions in Response to the COVID–19 Public Health Emergency” in the May 3, 2021 *Federal Register* (86 FR 23496) (referred to in this proposed rule as the “2021 CJR 3-Year Extension final rule”). The 2021 CJR 3-Year Extension final rule finalized the extension and modification of the original CJR Model that CMS had proposed in the 2020 CJR 3-Year Extension proposed rule. This rule extended the length of the model through December 31, 2024 by adding an additional 3 CJR Model PYs. Also, CMS finalized revisions to certain aspects of the CJR Model including the episode definition (which was modified to include outpatient episodes), the target price calculation, the reconciliation process, the beneficiary notice requirements, and the appeals process. In addition, for PYs 6 through 8, the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments for certain recipients was eliminated.

By 2024, CMS continued to believe the CJR Model could demonstrate savings after extending the model with

modifications to account for policy and practice pattern changes. However, assessing the impact of these modifications on the potential for certification and expansion of the CJR Model would require additional time to collect and analyze evaluation data. Although preliminary evaluation results for CJR Model PY6 suggested that the modifications would result in Medicare savings, preliminary evaluation results for the full 3-year CJR Extension would not be available until late 2025. In the meantime, CMS sought to continue the care transformation efforts that we had promoted through both the CJR and Bundled Payments for Care Improvement Advanced (BPCI Advanced) Models. To achieve this goal, CMS finalized the Transforming Episode Accountability Model (TEAM) in the FY 2025 IPPS/LTCH PPS final rule, which appeared in the August 28, 2024 *Federal Register* (89 FR 68986). TEAM is a mandatory episode-based payment model for selected acute care hospitals that includes five surgical episodes, including LEJR. As we noted in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69631), TEAM is based on: (1) lessons learned from testing the Bundled Payments for Care Improvement (BPCI) initiative, the BPCI Advanced Model, and the CJR Model; and (2) comments received from the “Request for Information; Episode-Based Payment Model” (88 FR 45872) published in the *Federal Register* on July 18, 2023. The first TEAM performance year began on January 1, 2026.

The LEJR episode and payment methodology currently being tested in TEAM are similar to the CJR Model in many ways, but there are a few key differences between the models. For example, TEAM episodes include the 30-day period after the discharge date (for inpatient procedures) or procedure date (for outpatient procedures), rather than the 90-day post-acute period included in the CJR Model. TEAM incorporates a more comprehensive set of risk adjustment factors into episode target prices as compared to the CJR Extension. TEAM also includes provisions for safety net hospitals (as defined at § 512.505) and hospitals with a low volume of episodes during the applicable baseline period to protect those hospitals from disproportionate financial risk. As stated previously, each element of TEAM that differs from either original CJR Model or the CJR Extension was included based on evaluation findings from the CJR and BPCI Advanced Models or stakeholder feedback, including responses to the

July 2023 “Request for Information; Episode-Based Payment Model”.

The final CJR Model PY ended on December 31, 2024, and the first TEAM performance year began on January 1, 2026. In the interim period between the end of the CJR Model and the beginning of TEAM, final evaluation results for the CJR Model PYs 6 and 7 and preliminary evaluation results for CJR Model PY 8 became available, due to the time required after a given CJR Model PY to allow for claims run out, the reconciliation process, and data analysis. Evaluation results for CJR Model PYs 6 through 8 indicated that the modifications in the CJR Extension, along with the more targeted application of the extreme and uncontrollable circumstances policy to COVID–19 episodes, had succeeded in returning the CJR Model to a positive savings trajectory. The seventh annual evaluation report found that the CJR Model had produced \$112.7 million in net savings to Medicare across CJR Model PYs 6 and 7 while maintaining quality of care.<sup>462</sup>

Given the success of the CJR Model in achieving savings for Medicare across CJR Model PYs 6 through 8 while maintaining quality of care resulting from the CJR Extension policy modifications, CMS is proposing to expand the CJR Model to all eligible acute care hospitals nationwide. For hospitals currently participating in TEAM, which includes an LEJR episode, CMS is proposing that those TEAM participant hospitals would be exempt from CJR–X until the end of the TEAM model test. We are proposing minor modifications in CJR–X that will align with some of the policies we implemented in TEAM because we believe these changes represent improvements to the CJR Model methodology, as we discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69631) and will discuss in further detail in the following sections of this proposed rule. We are proposing to codify CJR–X policies at §§ 512.600 through 512.695, as discussed in more detail in the sections that follow.

#### c. Requirements for Expansion of the CJR Model

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis), through rulemaking, the duration and the scope of a model that is being tested under section

<sup>461</sup> Comprehensive Care for Joint Replacement Model—Fifth Annual Report (<https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-annual-report>).

<sup>462</sup> Comprehensive Care for Joint Replacement Model—Seventh Annual Report (<https://www.cms.gov/priorities/innovation/data-and-reports/2025/cjr-py7-annual-report>).

1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) the Secretary determines that such expansion is expected to reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that such expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits.

- *Reduced Spending while Maintaining Quality of Care:* As observed in the Seventh Annual Evaluation Report, the CJR Model achieved savings to Medicare of \$112.7 million across PY 6 and 7 while maintaining quality of care as measured by emergency department (ED) visits, unplanned readmission rates, mortality rates, and LEJR complication rates.<sup>463</sup> Based on these findings, the Secretary determined that expansion of the CJR Model would reduce spending while maintaining quality of care.

- *Impact on Medicare Spending:* The CMS Chief Actuary has certified that expansion of the CJR Model would produce Medicare savings if expanded to all eligible acute care hospitals nationwide.

- *No Alteration in Coverage or Provision of Benefits:* The CJR Model did not make any changes to coverage or provision of benefits for beneficiaries. Therefore, the Secretary has determined that expansion of the CJR Model would not deny or limit the coverage or provision of Medicare benefits for beneficiaries.

Consistent with our statutory authority, we propose to continue to test and evaluate the CJR Model as CJR-X. We note that CJR-X would not be considered a Phase I model, as described under section 1115A(b) of the Act, but rather it would be a Phase II model under section 1115A(c) of the Act. As a nationally expanded Phase II model, we would continue to assess whether the expanded implementation of CJR-X is either continuing to reduce Medicare spending without reducing quality of care or improving the quality of patient care without increasing spending. We note that we may modify CJR-X as appropriate through future notice and comment rulemaking.

## 2. Provisions of the Proposed Comprehensive Care for Joint Replacement Expanded (CJR-X) Model

### a. Scope of Proposed Model

We propose that CJR-X would begin on October 1, 2027. Under this proposal, CJR-X performance years would align with fiscal years (FYs), in contrast the CJR Model, which aligned with calendar years (CYs). While we considered proposing a January 1, 2028 start date to align with CY and be consistent with the CJR Model, we believe that changing to FY is more appropriate given that the IPPS is aligned to an FY cycle, and we anticipate potential future policy changes to CJR-X would be proposed in the IPPS rulemaking cycle. Therefore, we propose that the first PY of CJR-X would run from October 1, 2027 through September 30, 2028, and the proceeding performance years would follow the same cadence.

We also considered a later start date to allow additional time for CJR-X participants to prepare for the model. However, we believe it beneficial to limit the amount of time between the final CJR Model PY and the continuation of the model test as CJR-X. In addition, the proposed start date provides more lead time for participants than the CJR Model did when finalized in November 2015. Despite the CJR Model beginning when hospitals had less experience with episode-based payment models, participants were able to successfully implement the model for the first performance year in April 2016. With the October 1, 2027 start date, hospitals would have more than 1 year to prepare for CJR-X participation. We also anticipate that many hospitals will have prior experience with LEJR episodes given that the Innovation Center has tested episode-based payment models for over a decade and Medicare Advantage organizations and commercial insurers often include episode-based contracts for high-volume procedures. We seek comment on our proposal at § 512.605 to define “performance year” as aligning with FYs and our proposal at § 512.630(a) to begin the model on October 1, 2027. We also seek comment on alternative start dates.

The CJR Model was a mandatory model for acute care hospitals within certain selected MSAs. However, for CJR-X, we propose that all eligible acute care hospitals nationwide would be required to participate, as described in section X.C.1.b. of this proposed rule. As we stated in section X.C.1.c. of this proposed rule, the CJR Model has met the requirements for expansion as a nationwide model by reducing spending

and maintaining quality of care among mandatory hospitals, and the CMS Chief Actuary has certified its nationwide expansion as a mandatory model.

### b. Proposed Participants

#### (1) Background

The CJR Model incentivized coordination between hospitals, clinicians, and PAC providers (that is, home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs), as defined at section 1899B(a)(2) of the Act) to improve outcomes and reduce spending for beneficiaries undergoing an LEJR procedure. The model required participation by most acute care hospitals in selected geographical areas, unless they met certain exceptions. Based on the CJR Model evaluations, participant hospitals were able to decrease spending while maintaining quality. Therefore, we believe expanding the model nationally to all eligible hospitals would increase the impact of CJR-X.

#### (2) Proposed CJR-X Participant Definition

Consistent with the CJR Model, we propose that hospitals would be the model participants in CJR-X. Because it is the hospital that furnishes the surgical procedure, we believe it is most straightforward and appropriate for the hospital to be the model participant. Hospital staff already manage discharge needs and placement recommendations as part of post-procedural or post-discharge care for beneficiaries. In addition, hospitals are more likely than other providers or suppliers to have access to the resources to appropriately manage and coordinate care throughout the episode and have an adequate volume of episodes to warrant investment in more robust care coordination. For the purposes of CJR-X, the term “hospital” means a hospital as defined in section 1886(d)(1)(B) of the Act, which includes only acute care hospitals and excludes certain specialty hospitals, such as psychiatric and cancer hospitals. Although the CJR Model was confined to certain geographic areas, we propose at § 512.610(a) that CJR-X participation would be mandatory for all acute care hospitals nationwide, provided they meet the proposed “CJR-X participant” definition.

We propose to define a “CJR-X participant” as an acute care hospital located in any of the 50 United States, District of Columbia, or U.S. Territory that initiates LEJR episodes and is paid

<sup>463</sup> Ibid.

under both the IPPS and OPPIs, unless it meets an exception described in section X.C.2.b.(i.) of this proposed rule. We believe that only including acute care hospitals that bill for services under both the IPPS and OPPIs is necessary to avoid potential challenges related to constructing target prices for episodes that initiate in either the inpatient or outpatient department of a hospital but are not paid under the IPPS or OPPIs, respectively. For instance, this policy would exclude Indian Health Service (IHS) and Tribal hospitals from CJR-X participation as they are paid under the IPPS but not the OPPIs, as described in § 419.20 of this chapter. Similarly, hospitals participating in the Rural Community Hospital Demonstration, Critical Access Hospitals, and Rural Emergency Hospitals would also be excepted because they are not paid under IPPS.

Further, we propose at § 512.610(a)(2) that CJR-X participants will remain CJR-X participants, unless they no longer meet the definition of CJR-X participant, CMS terminates CJR-X or the CJR-X participant receives notice of termination from CJR-X in accordance with § 512.165.

We considered but did not propose including Ambulatory Surgery Centers (ASCs) as CJR-X participants. Including ASCs would present a significant departure from the CJR Model test and introduce overwhelming uncertainty to the CMS Chief Actuary's certification. We note that CMS issued a request for information regarding ASC inclusion in TEAM in section X.A.2.d. of this proposed rule. Should ASCs be included in TEAM in the future and subsequent TEAM evaluation reports produce data to support ASC inclusion in CJR-X, any such participation change would be proposed through future notice and comment rulemaking.

We seek comment on our proposal at § 512.605 to define "hospital" as defined in section 1886(d)(1)(B) of the Act and "CJR-X participant" as a hospital located in any of the 50 States, District of Columbia, and U.S. Territories that initiates LEJR episodes and is paid under both the IPPS and OPPIs. We also seek comment on our proposals at § 512.610(a) that CJR-X participation would be mandatory for all eligible acute care hospitals nationwide and that CJR-X participants will remain CJR-X participants, unless they no longer meet the definition of CJR-X participant, CMS terminates CJR-X, or the CJR-X participant receives notice of termination from CJR-X in accordance with § 512.165.

#### (a) Proposed CJR-X Participant Exceptions

We propose at § 512.610(b)(1) to exclude hospitals that are TEAM participants. Although LEJR episodes in TEAM are similar to the proposed LEJR episodes in CJR-X, there are a few key differences. Most notably, TEAM tests 30-day episodes, while CJR-X would continue testing 90-day episodes that demonstrated savings in the CJR Model. Excluding TEAM participants from CJR-X would allow us to compare the impacts of 30- and 90-day episodes on savings and quality of care, while maintaining a consistent methodology across all five TEAM episodes. Moreover, we believe that subjecting TEAM participants to CJR-X rules for LEJR episodes and TEAM rules for the remaining four TEAM episodes would create confusion for providers and deviate from a consistent testing methodology.

We note that the TEAM exclusion applies to both mandatory and voluntary TEAM participants, as voluntary TEAM participants must remain in the model until its conclusion per § 512.510(a). We also note that this exclusion would expire at the conclusion of the TEAM test or if at any point a TEAM participant no longer meets the TEAM participant definition, at which point TEAM participants that meet CJR-X participant definition at § 512.605 would become CJR-X participants. In addition, while it is too early to make assumptions about the model test, should TEAM be expanded in the future, we would evaluate whether to continue LEJR in either TEAM or CJR-X, as we do not envision LEJR episodes being expanded in both concurrently.

We propose at § 512.610(b)(2) to exclude acute care hospitals in the State of Maryland because of its unique rate-setting authority, as described in section X.C.2.f.(3)(a) of this proposed rule. We do not believe that the regional pricing methodology used in CJR-X would accurately reflect episode spending for Maryland hospitals. We acknowledge that the State of Maryland is participating in the Achieving Healthcare Efficiency through Accountable Design (AHEAD) model, with which CJR-X would allow concurrent participation. Further, we are aware that Maryland's rate setting authority is in transition and will conclude at the end of 2027. Therefore, we may consider, through future notice and comment rulemaking, modifications to our proposed policy to exclude Maryland from CJR-X and our proposed

policy to permit concurrent participation with the AHEAD model.

We seek comment on our proposals at § 512.610(b) to exclude TEAM participants and Maryland hospitals from CJR-X.

#### c. Proposed Beneficiary Population

We propose at § 512.620(a) that the beneficiaries whose care would be included in CJR-X would include those who meet the following beneficiary inclusion criteria at the time of their admission for an anchor procedure or anchor hospitalization:

- Is enrolled in Medicare Part A and Part B;
- Has Medicare as their primary payer;
- Is not eligible for Medicare on the basis of end-stage renal disease, as described at § 406.13;
- Is not enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost-based health maintenance organizations);
- Is not covered under a United Mine Workers of America health plan, which provides health care benefits for retired mine workers; and
- Is in an episode, as defined at § 512.605.

We believe this is the most appropriate Medicare population to include in CJR-X because it aligns with the CJR Model population tested. Excluding beneficiaries enrolled in managed care or covered by payment systems other than the IPPS and OPPIs ensures that CMS has complete and consistent claims data across the full episode of care, including inpatient, outpatient, physician, and post-acute services, which is essential for setting target prices, calculating episode spending, and assessing quality performance. In addition, excluding beneficiaries with Medicare eligibility based on end-stage renal disease and those with other primary payers helps reduce clinical and financial heterogeneity that could compromise comparability across episodes and participant hospitals. Together, these eligibility criteria ensure that CJR-X hospitals are held accountable only for episodes over which Medicare has primary payment responsibility and complete data visibility.

We recognize that a CJR-X episode could be initiated for a beneficiary who ceases to meet the beneficiary inclusion criteria at some point during the episode. In this case, we propose at § 512.620(b) that we would cancel the episode. We seek comment on the proposed beneficiary inclusion criteria and the proposal to cancel episodes if a

beneficiary no longer meets that criteria at § 512.620.

#### (1) Beneficiary Notification

We are proposing CJR-X because we believe it offers an opportunity to improve quality of care. We believe that the policies of the model would make care more easily accessible to consumers when and where they need it and increase consumer engagement and beneficiary choice. For example, under this model we are proposing certain waivers which would offer CJR-X participants additional flexibilities with respect to furnishing telehealth services and care in SNFs, as discussed in section X.C.2.j. of this proposed rule. Conversely, we do note that these same opportunities could be used to try to steer beneficiaries into lower cost services without an appropriate emphasis on maintaining or increasing quality given the incentives to reduce Medicare spending in the model.

We believe that existing Medicare provisions would be effective in protecting beneficiary freedom of choice and access to appropriate care under CJR-X. Further, since CJR-X would be expanded nationally, diverting care to hospitals not in the model would be less of an issue given CJR-X's broad scale. Because we have proposed mandatory hospital participation, individual beneficiaries would not be able to opt out of CJR-X when they receive care from a CJR-X participant. Moreover, allowing beneficiaries to opt out would be inconsistent with other Medicare policies. For example, we do not allow beneficiaries to opt out of a payment system, such as the IPPS. Moreover, we do not believe that an ability to opt out of a payment system is a critical factor in upholding beneficiary choice if other safeguards are in place. Specifically, we do not believe this would be an issue for CJR-X, given that this model does not increase beneficiary cost-sharing. However, CJR-X beneficiaries are not precluded from seeking care from providers or suppliers who do not participate in CJR-X. We do believe that full notification and disclosure of the payment model and its possible implications is critical for CJR-X beneficiary understanding and protection. It is important to create safeguards for CJR-X beneficiaries to ensure that care recommendations are based on clinical needs and not inappropriate cost savings. It is also important for CJR-X beneficiaries to know that they can raise any concerns with their clinicians, with 1-800-MEDICARE, or with their local Quality Improvement Organizations (QIOs).

This proposed CJR-X model would neither limit a CJR-X beneficiary's ability to choose providers nor limit Medicare's coverage of items and services available to the CJR-X beneficiary. CJR-X beneficiaries may continue to choose any Medicare participating provider, or any provider who has opted out of Medicare, with the same costs, copayments and responsibilities as they have with other Medicare services. As proposed in section X.C.2.(m) of this proposed rule, CJR-X participants would be subject to the standard provisions at §§ 512.100 through 190, including the beneficiary protections noted in § 512.120 that cover beneficiary freedom of choice, availability of services, and descriptive model materials and activities.

Further, the proposed model would allow CJR-X participants to enter into CJR-X sharing arrangements with certain providers, as proposed in section X.C.2.i.(4) of this proposed rule, and these preferred providers may be recommended to CJR-X beneficiaries as long as those recommendations are made within the constraints of current law. However, CJR-X participants may not limit CJR-X beneficiaries to a preferred or recommended providers list that is not compliant with restrictions existing under current statutes and regulations.

Moreover, as proposed in section X.C.2.i.(3) of this proposed rule, CJR-X participants may not charge any CJR-X collaborator a fee to be included on any list of preferred providers or suppliers, nor may the hospital accept such payments, which would be considered to be outside the realm of risk-sharing agreements. Thus, this proposed payment model does not create any restriction of beneficiary freedom to choose providers, including surgeons, hospitals, post-acute care or any other providers or suppliers. Moreover, we anticipate that care pathway redesign occurring in response to the model will increase coordination of care, improve the quality of care, and decrease cost for all patients, not just for Medicare beneficiaries. As it would be unlikely that providers would treat individuals differently based on health care insurance, we anticipate care delivery impacts to promote consistent treatment of all beneficiaries.

We propose at § 512.622(a)(1) that every CJR-X participant must provide written notification to each CJR-X beneficiary of his or her inclusion in the CJR-X model. We believe that appropriate beneficiary notification should explain the model, advise patients of both their clinical needs and their care delivery choices, and should

clearly identify any CJR-X collaborator, as defined at § 512.605. That is, the CJR-X participant would be required to disclose any providers, suppliers, or other entities with which the CJR-X participant holds a sharing arrangement as a "financial partner of the hospital for the purposes of participation in CJR-X."

We believe that this notification would enhance CJR-X beneficiaries' understanding of their care and is an important safeguard for ensuring CJR-X beneficiaries receive all medically necessary services. It is also an important clinical opportunity to better engage CJR-X beneficiaries in shared decision-making and understanding competing benefits, even as they are presented with cost-saving recommendations. Therefore, we propose at § 512.622(a)(4) that the CJR-X beneficiary notification must:

- Explain the CJR-X model and how it might be expected to affect the CJR-X beneficiary's care;
- Inform CJR-X beneficiaries that they retain freedom of choice to choose providers, suppliers, and services;
- Explain how the CJR-X beneficiary can access care records and claims data through an available patient portal and through sharing access to care-givers to their Blue Button® electronic health information;
- Explain that CJR-X participants may receive beneficiary-identifiable claims data;
- Advise CJR-X beneficiaries that all standard Medicare beneficiary protections remain in place, including the ability to report concerns of substandard care to QIOs and 1-800-MEDICARE; and
- Provide a list of the CJR-X collaborators with which the CJR-X participant has a sharing arrangement.

We recognize that an exhaustive list of CJR-X collaborators may lengthen the beneficiary notification, unnecessarily. Therefore, this requirement may be fulfilled by the CJR-X participant including in the detailed notification a publicly available web address where CJR-X beneficiaries may access the CJR-X collaborators list.

After carefully considering the appropriate timing and circumstances for the necessary CJR-X beneficiary notification, we are proposing at § 512.622(a)(2) that CJR-X participants must provide the CJR-X beneficiary notification prior to discharge from either the anchor hospitalization or the anchor procedure for a Medicare beneficiary who would be included under the model. The purpose of this proposed policy is to ensure that all CJR-X beneficiaries receive the beneficiary notification materials, and



that they receive such materials as early as possible but no later than discharge from the hospital or hospital outpatient department. We believe that this proposal increases the likelihood that patients will become engaged and seek to understand CJR–X and its potential impact on their care, particularly in the post-discharge period.

We also considered whether to require CJR–X participants to provide this information at the point of admission, as hospitals provide other information concerning patient rights and responsibilities at that time. However, we recognize that, due to a CJR–X beneficiary's condition, it may not be feasible to provide notification at such time. We invite comment on ways in which the timing and source of beneficiary notification could best serve the needs of CJR–X beneficiaries without creating unnecessary administrative work.

In addition, we propose at § 512.622(b) that CJR–X participants must require every CJR–X collaborator to provide written notice, to applicable CJR–X beneficiaries that describes the existence of a sharing arrangement with the CJR–X participant and the basic quality and payment incentives under the model. We propose that the notice must be provided no later than the time at which the beneficiary first receives an item or service from the CJR–X collaborator during an episode. We recognize that due to the patient's condition, it may not be feasible to provide notification at such time, in which case the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. If the beneficiary notification policy is finalized, CMS would post a CJR–X collaborator template for use by CJR–X participants on the CJR–X website.

We considered, but are not proposing, requiring the CJR–X beneficiary notifications only during the years that both CJR–X and TEAM are implemented. After TEAM ends, then we would no longer require CJR–X beneficiary notifications since all hospitals nationwide, barring any excluded hospitals from CJR–X, would be held accountable for LEJR episodes. We also considered, but are not proposing, not requiring the CJR–X beneficiary notifications. We acknowledge other CMS initiatives, such as the Hospital Value Based Purchasing Program or the Expanded Home Health Value-Based Purchasing Model, do not require entities participating in those initiatives to provide beneficiary notifications. We recognize a model that is expanded

nationally, such as the proposed CJR–X, would become standard practice for hospitals to manage beneficiaries in a LEJR episode of care. Therefore, the beneficiaries' experience or treatment options should not materially change between participating hospitals, nor would beneficiaries' or out-of-pocket costs, freedom of choice, or access to care differ. Further, we recognize that beneficiaries already receive a significant amount of information on discharge from the hospital or hospital outpatient department and a beneficiary notification may go unnoticed or be redundant. That is because we believe the CJR–X participant would already be communicating to the CJR–X beneficiary the hospital's responsibility to manage the CJR–X beneficiary during the episode, including in the 90-day post-discharge period. Thus, the administrative burden of notification may outweigh its value.

We invite public comment on our proposed requirements for notification to CJR–X beneficiaries at § 512.622. We also seek comment on our consideration to not require CJR–X beneficiary notifications.

#### d. Proposed Episode

##### (1) Background

A key design feature of episode-based payment models is the definition of the episodes included in the model. The episode definition has two significant dimensions—(1) a clinical dimension that describes which clinical conditions and associated services are included in the episode; and (2) a time dimension that describes the beginning and end of the episode, its length, and when the episode may be cancelled prior to the end of the episode.

In testing payment models, we recognize the importance of there being clear potential for participating hospitals to successfully drive care improvements by streamlining care pathways and transitions between clinical settings. We aim to design models with episodes that are clinically similar, for which episode spending is more predictable. We also note that episodes with a greater proportion of spending in the post-acute period relative to the anchor hospitalization or procedure offer greater opportunity for improved care transitions for beneficiaries to reduce unnecessary hospitalizations and emergency care.

Given the promising findings for LEJR in the CJR Model and BPCI Advanced, we believe there is value in an expansion of the CJR Model test through CJR–X, particularly given the high volume of LEJR procedures among the

Medicare population. Based on 2021 Medicare claims data, LEJR episodes were the highest volume, highest cost of the BPCI Advanced surgical episode categories. There were 204,160 episodes with a total cost of \$5.01 billion, with more than 40 percent of spending occurring in the post-acute period. Moreover, based on the CJR Model evaluation, LEJR episodes continue to offer opportunities for improvement.

#### (2) Clinical Dimension of Episode

##### (a) Episode Definition (LEJR)

We propose to define “episode” to mean all Medicare Part A and B items and services described in § 512.625(b) (and excluding the items and services described in § 512.625(c)) that are furnished to a beneficiary described in § 512.620 during the time period that begins on the date of the beneficiary's admission to an anchor hospitalization or the date of the anchor procedure, as described at § 512.625(a), and ends on the 90th day following the date of discharge from the anchor hospitalization or anchor procedure, with the date of discharge or date of the anchor procedure itself being counted as the first day in the 90-day post-discharge period, as described at § 512.630. In the case that an anchor hospitalization for the same episode type occurs within 3 days of an anchor procedure (for example, an outpatient procedure is later converted to an inpatient admission), the anchor procedure episode is canceled, and the episode start date for the anchor hospitalization is the same as the outpatient procedure. This episode definition aligns with the CJR Model and with TEAM, at § 510.2 and § 512.505, respectively, which provides consistency across Innovation Center models. In addition, this proposed policy aligns with Medicare's 3-day payment guidelines that require hospitals to bundle the technical component of outpatient services with the inpatient claim if they are related to the same condition and occur in the 3 days preceding inpatient admission, in compliance with section 1886 of the Act.

We seek comment on our proposed episode definition at § 512.605.

##### (b) Episode Identification (MS–DRG/ HCPCS)

We believe that a straightforward approach for identifying CJR–X episodes is important for the care redesign that is required for model success. As was done in the CJR Model, hospitals participating in the proposed CJR–X would be able to identify episodes



through the MS-DRG of the anchor hospitalization or by the Healthcare Common Procedure Coding System (HCPCS) codes for hospital outpatient procedures, allowing active coordination of beneficiary care during and after the anchor procedure or anchor hospitalization. We believe identifying LEJR episodes with MS-DRGs or HCPCS codes is a reasonable approach especially given LEJR is a procedural episode, making CJR-X beneficiary identification easier at the time of hospital inpatient or hospital outpatient department admission. This approach offers operational simplicity for providers and CMS, and is consistent with the approach taken by BPCI Advanced and the CJR Model to identify beneficiaries whose care is included in those episodes. We note that there may be times an episode initiating code, such as an included MS-DRG, changes after the CJR-X beneficiary is discharged. For example, the inpatient LEJR procedure generally determines the ultimate MS-DRG assignment for the hospitalization. However, depending on the beneficiary's principal and secondary diagnoses and other procedures received during the inpatient stay, the final MS-DRG assigned to the inpatient stay may not be the LEJR procedure, then the episode would not be picked up for CJR-X.<sup>464</sup> In those instances, CJR-X participants could rely on data shared by CMS, in accordance with a CJR-X data sharing agreement and attestation, to confirm episode attribution, as described in section X.C.2.k. of this proposed rule.

We propose to identify LEJR episodes by certain MS-DRGs and HCPCS codes included on claims. Specifically, IPPS discharges under MS-DRG 469, 470, 521, or 522; and OPPS claims for HCPCS codes 27130 or 27447, would trigger LEJR episodes in CJR-X. This approach offers operational simplicity for both providers and CMS and is consistent with the approach taken by previous models to identify episodes.

We seek comment on our proposal at § 512.625(a) to identify LEJR episodes with MS-DRGs and HCPCS in CJR-X.

### (3) Scope of Episode

We propose that, consistent with the CJR Model, LEJR episodes in CJR-X would include inpatient hip, knee, and ankle replacement procedures paid

through the IPPS under select MS-DRGs and hospital outpatient hip and knee replacement procedures billed under select HCPCS codes through the OPPS. We propose to exclude from CJR-X ankle replacements performed in the outpatient setting. Total ankle arthroplasty (TAA) was on the IPO list until 2021 and, therefore, was not included in BPCI Advanced or the CJR Model. Although we did consider including outpatient TAAs in CJR-X, to do so at this time would represent too great a departure from the CJR Model to meet the limits of OACT certification. However, we are currently testing outpatient TAAs, as identified by HCPCS code 27702, in TEAM. If we consider adding outpatient TAAs to CJR-X at some point in the future based on TEAM evaluations, we would propose that change through notice and comment rulemaking.

We seek comment on the MS-DRG and HCPCS codes proposed for inclusion in CJR-X at § 512.625(a) and our proposal to exclude outpatient TAA from the LEJR episode category.

#### (a) Episode Initiation

We propose that, if a beneficiary meets the beneficiary inclusion criteria at § 512.620, an LEJR episode would begin when a beneficiary is admitted for an anchor hospitalization for one of the following MS-DRGs or an anchor procedure indicated by one of the following HCPCS codes on an outpatient claim (specifically, a hospital's institutional claim for an included outpatient procedure billed through the OPPS):

MS-DRGs and HCPCS—

- 469 (Major joint replacement or reattachment of lower extremity with major complications or comorbidities (MCC)).
- 470 (Major joint replacement or reattachment of lower extremity without MCC).
- 521 (Hip replacement with principal diagnosis of hip fracture with MCC).
- 522 (Hip replacement with principal diagnosis of hip fracture without MCC).
- 27447 (Total knee arthroplasty).
- 27130 (Total hip arthroplasty).

We propose that the episode start date would be the day of the anchor procedure for outpatient procedures and the date of admission for an inpatient hospitalization. However, if an anchor hospitalization is initiated on the same day as or within 3 days of an outpatient LEJR procedure, we propose to begin the episode on the date of the outpatient procedure rather than the date of the inpatient admission.

We recognize there could potentially be episodes initiated as a result of a beneficiary being transferred from one CJR-X participant hospital to another. In this case, and in alignment with the CJR Model and TEAM, these would be viewed as two separate hospitalizations. Specifically, if the initial inpatient admission is for an MS-DRG in CJR-X, then a transfer to another hospital would not initiate a new anchor hospitalization, rather it would be included in the LEJR episode initiated from the first hospitalization. However, if a beneficiary is admitted to a hospital for an MS-DRG not included in CJR-X, and subsequently transferred to another CJR-X hospital from which they are discharged under an MS-DRG that is included in CJR-X, the second hospitalization would initiate the LEJR episode at the second CJR-X hospital.

We seek comment on our proposal at § 512.630(c) for initiating CJR-X episodes.

#### (b) Items and Services Included in the Episode

Like previous episode-based payment models, CJR-X would incentivize comprehensive, coordinated, patient-centered care through inclusive episodes. We propose to include in the episode all items and services paid under Medicare Part A and Part B during the performance period, unless such items and services fall under a proposed exclusion described in section X.C.2.d.(3)(c) of this proposed rule.

We propose to include all Part A services furnished during the 90-day post-discharge period of the episode, other than certain excluded hospital readmissions, as including post-discharge Part A services, such as post-acute care, would ensure the episode is comprehensive in nature. In particular, we believe that claims for services with diagnosis codes that are directly related to LEJR episodes or the quality and safety of care furnished during the episode (for example, surgical wound infection) should be included in an episode. Thus, we propose that items and services for episodes would include all items and services paid under Medicare Part A and Part B, subject to the proposed exclusions in section X.C.2.d.(3)(c) of this proposed rule. For example, the following is a non-exhaustive list of services included in episodes:

- Physicians' services.
- Inpatient hospital services, including services paid through IPPS operating and capital payments.
- Inpatient psychiatric facility (IPF) services.

<sup>464</sup> Medical Severity Diagnosis Related Groups (MS-DRGs): Definitions Manual, Version 33.0A. 3M Health Information Systems. (October 1, 2015). <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html>.

- Long-Term Care Hospital (LTCH) services.
- Inpatient Rehabilitation Facility (IRF) services.
- Skilled Nursing Facility (SNF) services.
- Home Health Agency (HHA) services.
- Hospital outpatient services.
- Outpatient therapy services.
- Clinical laboratory services.
- Durable medical equipment.
- Part B drugs and biologics except for those excluded under § 512.625(c) as proposed.

- Hospice services.
- Part B professional claims dated in the 3 days prior to an anchor hospitalization if a claim for the surgical procedure is not detected as part of the hospitalization because the procedure was performed by the participant on an outpatient basis but the patient was subsequently admitted as an inpatient.

These items and services are similar to those included in the CJR Model and reflect the full range of Medicare-covered services that would be furnished to a CJR-X beneficiary during an episode. As joint replacement episodes frequently involve services across multiple providers and settings, we believe excluding these services would fragment financial accountability and undermine the model's ability to promote care coordination and cost containment. Moreover, including these services aligns incentives for hospitals to manage transitions of care, post-acute utilization, and complication-related services.

We seek comment on the items and services we are proposing to include in CJR-X at § 512.625(b).

#### (c) Excluded Items and Services

We propose to exclude from episodes certain Part A and B items and services that are clinically unrelated to an LEJR procedure. The proposed exclusions would be applicable to episodes included during the baseline period, the three-year historical period used to construct target prices, as described in section X.C.2.f.(3)(a), of this proposed rule, and episodes initiated during a performance year. We propose to use these exclusions based on several years of experience with them and their suitability for LEJR episodes. The rationale for the proposed exclusions is consistent with the rationale for exclusions in the CJR Model (80 FR 73303) and TEAM (89 FR 69722) but differ slightly from both.

We propose to exclude from episodes all Part A and B items and services for hospital admissions and readmissions, for both the baseline period and

performance years, for specific categories of diagnoses, such as oncology, trauma medical admissions, organ transplant, and ventricular shunts determined by MS-DRGs, as well as all of the following excluded Major Diagnostic Categories (MDC):<sup>465</sup>

- MDC 02 (Diseases and Disorders of the Eye).
- MDC 14 (Pregnancy, Childbirth, and Puerperium).
- MDC 15 (Newborns).
- MDC 25 (Human Immunodeficiency Virus).

We propose to exclude from episodes IPPS new technology add-on payments for drugs, technologies, and services identified by value code 77 on IPPS hospital claims for episodes in the baseline period and performance years.<sup>466</sup> New technology add-on payments are made separately and in addition to the MS-DRG payment under the IPPS for specific new drugs, technologies, and services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid under the MS-DRG system. We believe this exclusion would reduce the potential for CJR-X to diminish beneficiaries' access to new technologies or burden hospitals with concern about the payments for these new drugs, technologies, or services counting toward CJR-X participants' actual episode spending. Additionally, new drugs, technologies, or services approved for the add-on payments vary unpredictably over time in their application to specific clinical conditions. In addition, maintaining this exclusion from CJR-X episodes would align with the CJR Model (80 FR 73303 through 73304 and 73315).

We also propose to exclude from episodes OPPS transitional pass-through payments for medical devices as identified through OPPS status indicator H for episodes in the baseline period and performance years. Through the established OPPS review process, we have determined that these technologies have a substantial cost but also lead to substantial clinical improvement for Medicare beneficiaries. This proposal is consistent with the CJR Model final exclusions policy (80 FR 73308 and 73315).

We propose to exclude hemophilia clotting factors (§ 412.115), identified

<sup>465</sup> MDCs are formed by dividing all possible principal diagnoses (from ICD-10-CM) into 25 mutually exclusive diagnosis areas. The diagnoses in each MDC correspond to a single organ system or etiology and in general are associated with a particular medical specialty.

<sup>466</sup> This exclusion is applied during the payment standardization process.

through HCPCS code, diagnosis code, and revenue center on IPPS claims for episodes in the baseline period and performance years. In contrast to other drugs and biologics that are administered during an inpatient hospitalization and paid through the MS-DRG, hemophilia clotting factors are paid separately by Medicare in recognition of clotting factors being costly, yet essential, to care for certain beneficiaries. Because we do not believe that there are any spending efficiencies to be gained by including hemophilia clotting factors, we propose to exclude these high-cost drugs from episodes initiated during the baseline period and performance year.

We also propose to exclude from episodes certain Part B payments for high-cost drugs and biologics, low-volume drugs, and blood clotting factors for hemophilia patients billed on outpatient, carrier, and durable medical equipment claims for episodes in the baseline period and initiated in the performance years.<sup>467</sup> These high-cost items are essential to appropriate care of certain beneficiaries and we do not believe including them in the episode would improve any spending or quality of care efficiencies. Specifically, this proposed list would include all of the following:

- For episodes included during the baseline period—
  - ++ Drug/biologic HCPCS codes that are billed in fewer than 31 episodes in total across all episodes in CJR-X during the baseline period;
  - ++ Drug/biologic HCPCS codes that are billed in at least 31 episodes in the baseline period, and have a mean allowed cost of greater than \$25,000 per episode in the baseline period; and
  - ++ HCPCS codes corresponding to clotting factors for hemophilia patients, identified in the quarterly average sales price file for certain Medicare Part B drugs and biologics as HCPCS codes with clotting factor = 1, HCPCS codes for new hemophilia clotting factors not in the baseline period, and other HCPCS codes identified as hemophilia.<sup>468</sup>
- For episodes initiated during a performance year, in addition to those listed in the previous bullet, Part B payments for high-cost drugs and biologics, low-volume drugs, and blood clotting factors for hemophilia billed on outpatient, carrier, and durable medical equipment (DME) claims, including, but not limited to—

<sup>467</sup> To determine if a drug HCPCS meets the cost or volume thresholds for exclusion, the episodes are pooled across all episode categories.

<sup>468</sup> <https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files>.

++ Drug/biologic HCPCS codes that were not included in the baseline period, and appear in 10 or fewer episodes in the performance year;

++ Drug/biologic HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the performance year, have a mean cost of greater than \$25,000 per episode in the performance year;

++ Drug/biologic HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the performance year, have a mean cost of \$25,000 or less per episode in the performance year, and correspond to a drug/biologic that appears in the baseline period list but was assigned a new HCPCS code between the baseline period and performance year; and

++ HCPCS codes for new hemophilia clotting factors not in the baseline period.

Complete lists of proposed excluded MS-DRGs for readmissions and proposed excluded HCPCS codes for Part B services furnished during episodes after beneficiary discharge from an anchor hospitalization would be posted on the CMS CJR-X web page within the Innovation Center website at <https://innovation.cms.gov>. The methodology to identify excluded items and services would apply to all performance years of the model, and lists would be shared with CJR-X participants on the CJR-X web page around the time preliminary target prices are released. Lists would be updated after the performance year concludes to account for the performance year exclusions proposed in the previous paragraph. We propose that revisions to the exclusion lists, such as adding MS-DRGs not covered by oncology, trauma medical admissions, organ transplant, and ventricular shunts, would be initiated through notice and comment rulemaking to allow for public input.

We seek comment on the proposed excluded services, the lists of excluded services, and the process for updating the lists of excluded services for CJR-X included in §§ 512.625(c), (d), and (e).

#### (d) Episode Duration

The proposed episodes would cover the surgical procedure and a subsequent period that is marked by significant PAC needs, potential complications of surgery, and short-term, intense management of chronic conditions that may be destabilized by a joint replacement. We believe that hospitals have substantial ability to influence the quality and efficiency of care that Medicare beneficiaries receive over the weeks and months following a

procedure. For this reason, the CJR Model utilized a 90-day post-discharge episode duration. It is during this period that beneficiaries are provided the most intensive care for their recovery, including physical therapy and interventions to prevent complications. Notably, the professional payments to the surgeon under the PFS for the procedures included in LEJR are also paid as a global payment covering a 90-day period.

The 90-day episode tested under the CJR Model demonstrated savings while maintaining quality, although some stakeholders have stated a shorter episode length would be more appropriate. Specifically, shorter episodes exhibit less spending variability due to medical events outside the intended scope of the model and conditions unrelated to the joint replacement become more prevalent in the later stage of an episode. In addition, longer episodes increase the potential for ACO overlap (where a beneficiary aligned or assigned to an ACO has an episode included in CJR-X). In the TEAM final rule (89 FR 69727), we agreed that a 30-day episode could position the specialist as the principal provider near the anchor event with a hand-off back to the primary care provider for longitudinal care management and we believe that ACOs are better equipped to address the population health needs of Medicare beneficiaries. For these reasons, the Innovation Center is currently testing a 30-day episode duration in TEAM. Through future evaluations and direct comparison between TEAM and CJR-X, we can determine the optimal episode length to balance spending reductions and outcomes.

Based on the rationale noted earlier, we propose to end episodes 90 days after discharge from the anchor hospitalization or anchor procedure and that day 1 of the 90-day post-acute portion of the episode is the date of the anchor procedure or the date of discharge from an anchor hospitalization. To the extent that a Medicare payment for services included in an episode spans a period of care that extends beyond the episode duration, we propose that these payments would be prorated so that only the portion attributable to care during the fixed duration of the episode is attributed to the episode spending.

We seek comment on our proposal at § 512.630(d) to maintain a 90-day post-discharge episode length.

#### (e) Episode Termination

Similar to the CJR Model, we propose that, once an episode begins, the

episode would continue until the end of the episode as described in section X.C.2.d.(3)(d). of this proposed rule, unless the episode is cancelled for certain reasons.

First, an episode would be canceled if the beneficiary ceases to meet any of the general beneficiary inclusion criteria described in section X.C.2.c. of this proposed rule. When a beneficiary's status changes during the episode, the episode target price would still reflect full payment for the episode. However, we would not have full Medicare episode payment data for the beneficiary to reconcile against the target price. Therefore, the episode would be canceled.

Second, in the case that a beneficiary has a subsequent inpatient admission for an episode on the same day as or within 3 days of an outpatient LEJR procedure, the outpatient episode would not initiate an anchor procedure and the outpatient procedure would instead initiate an anchor hospitalization. That is, the anchor hospitalization start date will be that of the outpatient procedure. We are proposing this policy because we believe that an inpatient episode should take precedence over an outpatient procedure performed on the same day, given the likelihood of higher spend associated with the inpatient episode and potential for higher clinical acuity.

Third, we propose to cancel the episode if a beneficiary dies at any point during the CJR-X episode. As discussed in the EPM proposed rule (81 FR 50841), we consider mortality to be a harmful beneficiary outcome that should be targeted for improvement through care redesign. We also believe holding participants responsible for episodes during which a beneficiary dies could encourage participants to actively reduce beneficiaries' risk of death. However, we acknowledge that the likelihood that a death that is unrelated to an LEJR procedure occurs is increased the further out from the anchor procedure or anchor hospitalization. Therefore, we believe that holding participants responsible for death during a 90-day episode would create too much uncertainty and variability for participants.

We note that TEAM only cancels episodes if death occurs during the anchor hospitalization or anchor procedure, but not if the death occurs in the post-discharge period (89 FR 69730). As we discussed in the CJR final rule (80 FR 73318), there would be limited incentive for efficiency that could be expected when death occurs during the anchor hospitalization itself. We considered aligning the CJR-X policy

with TEAM, but believe that this policy is appropriate for a 30-day episode where the cause of death during the post-discharge period is more likely to be related to the index procedure than in a 90-day episode. Therefore, we are not proposing for CJR–X to only cancel episodes for a death that occurs during the anchor hospitalization or anchor procedure. Rather, we would cancel any episode during which a death occurs during the anchor hospitalization, anchor procedure, or post-discharge period.

Finally, we propose that episodes subject to extreme and uncontrollable circumstances (EUC) would be canceled, meaning that the services associated with the episode would continue to be paid through Original Medicare, but the episode would not be reconciled against a target price. We propose to base the CJR–X EUC definition on the definition finalized in the CJR 2018 final rule (83 FR 26604), which was designed to address the extreme and uncontrollable costs associated with natural disasters such as hurricanes, flooding, and wildfires. Specifically, we propose that the EUC policy would apply to CJR–X participants with a CCN address located in a county where both: (1) a major disaster has been declared under the Stafford Act; and (2) section 1135 waivers have been issued. We believe that it is appropriate for our EUC policy to apply only in the narrow circumstance of a major disaster, which is catastrophic in nature and tends to have significant impacts on infrastructure, rather than the broader grounds for which an emergency could be declared.

We considered alternative approaches to EUC policy that would allow mandated participants to meet the model's objectives when one or more campuses of a hospital system is in a disaster area but would fail to meet the requirements set forth here. Specifically, we recognize that some hospital systems span across regions or state lines and a location that is not identified by the "CCN address" could be in a disaster area. Therefore, we considered alternative methods of identifying CJR–X participants at an individual level using NPI, TIN, or a combination of CCN and another identifier. While we are proposing to continue using CCN address until and unless an alternative is determined to be appropriate, any change would first be proposed through notice and comment rulemaking.

Separately, we acknowledge that stakeholders have requested that emergency flexibilities be extended to cybersecurity attacks. We also realize

that the difficulties such a scenario would cause for CJR–X participants would extend well beyond this model. Therefore, we would consider conforming to any future CMS policy that addresses emergent cybersecurity issues, as needed, through future notice and comment rulemaking.

We acknowledge this proposed EUC policy deviates from how the CJR Model addressed the COVID–19 PHE which fell under a major disaster declaration. During the PHE, the CJR Model effectively waived downside risk, which resulted in substantial losses to Medicare. We believe our proposed policy to cancel the episode, rather than waive downside risk, is a better long-term policy that avoids significant losses and gives flexibility to the CJR–X participant to manage a beneficiary's care and rely on FFS payments rather than be held accountable to spend below a target price. In regard to determining the start date of episodes to which the EUC would apply, we believe that episodes initiated during an emergency period or in the 30 days before the start date of an emergency period (as defined in section 1135(g) of the Act) should reasonably capture those beneficiaries whose high episode costs could be attributed to extreme and uncontrollable circumstances.

We also propose canceling a CJR–X episode if the beneficiary is in the 30-day post-discharge period following a TEAM anchor hospitalization or anchor procedure (that is, for an episode at a non-CJR–X hospital). Further discussion of this proposal is discussed in section X.C.2.h.(2). of this proposed rule.

In summary, we propose that the following circumstances would cancel an episode:

- The beneficiary no longer meets the criteria for inclusion.
- The beneficiary dies during the episode.
- The CJR–X participant is subject to the EUC policy.
- The beneficiary is in a TEAM episode and has a LEJR procedure at a CJR–X participant during the 30-day post-discharge period after a TEAM anchor hospitalization or anchor procedure.

When an episode is canceled, we propose that the services furnished to beneficiaries prior to and following the episode cancellation would continue to be paid by Medicare as usual but there would be no episode spending calculation that would be reconciled against the target price (see section X.C.2.f.(5). of this proposed rule). As discussed in section X.C.2.j. of this proposed rule, waivers of program rules applicable to beneficiaries in episodes

would apply to the care of beneficiaries who are in episodes at the time the waiver is used to bill for a service that is furnished, even if the episode is later canceled.

We seek comment on our proposal at § 512.630(e) to cancel episodes once they have begun but prior to the end of the 90-day post-discharge period under certain conditions.

## e. Proposed Quality Measures and Scoring

### (1) Background

The Medicare Modernization Act of 2003, the Affordable Care Act of 2010, and the Tax Relief and Healthcare Act of 2006 led to the implementation of several hospital quality reporting programs where payment reflects the quality of care delivered to Medicare beneficiaries. The CJR Model also tied quality to payment. We believe that future episode-based payment models, including the proposed CJR–X, should continue to link quality and payment to ensure ongoing incentives to improve patient outcomes and lower health care spending. This would be particularly important in an expanded model where some CJR–X participants will be new to episode-based payment models.

The CJR Model relied on data already reported to the Hospital Inpatient Quality Reporting (IQR) Program (section 1886(b)(3)(B)(viii) of the Act) to assess quality without additional reporting burden for CJR participants. Measures used in the CJR Model included a joint replacement-specific measure and a general patient experience survey of the hospital stay. Specifically, the CJR Model utilized the Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure, further discussed in Section X.C.2.e.(3) of this proposed rule. In addition to the two HIQR measures, the CJR Model offered participants an opportunity to receive additional points towards their quality score for voluntarily submitting THA/TKA patient-reported outcomes (PROs) and limited risk variable data following eligible elective primary THA/TKA procedures.

### (2) Selection of Proposed Quality Measures

We expect CJR–X will incentivize hospitals to engage in care redesign activities to reduce post-surgical complications and hospital readmissions and enhance patient

experience and outcomes for Medicare beneficiaries undergoing joint replacement surgery. Moreover, achieving savings while continuing to ensure high-quality care for Medicare beneficiaries will require close collaboration among hospitals, physicians, PAC providers, and other clinicians.

The quality measures we are proposing for CJR–X are a natural outgrowth of the CJR Model and maintain focus on patient safety, patient experience, and health outcomes for beneficiaries undergoing hip and knee arthroplasty. The proposed measures will sustain efforts to improve quality and health outcomes across a beneficiary's care journey and incentivize hospitals to better align and coordinate care across various programs and care settings. We believe the measures used for CJR (80 FR 73465 through 73507) remain appropriate for assessing care and propose to continue utilizing those measures for inpatient LEJR episodes in CJR–X. However, we propose two notable variations from the CJR Model measures, which are discussed in detail in sections X.C.2.e.(3). of this proposed rule.

First, we propose to weight the THA/TKA PRO more heavily. CMS is committed to increased use of PROs, whenever possible, as these measures provide valuable insights into the patient's perspective of care received. PROs assessing health status as a result of care are a critical type of outcome needed for health care quality assessment. The use of PRO measures (PROMs), standardized instruments that query patients' self-assessments of their health, provide a direct way to capture patients' experience of care and the results of that care. PROMs can assess multiple health domains, including physical health, emotional well-being, and social functioning through measuring outcomes relevant to each domain, such as symptoms, functional status, and mental status. As a result, they provide rich information on how care affects multiple dimensions of patients' well-being.

Broadly, patient-reported data includes PROs and electronic PROs (ePROs), which is the electronic capture of this data; PROMs, which reflect how the PRO data is reported (for example, a survey or questionnaire); and patient-reported outcome-based performance measures (PRO–PMs), which are reliable and valid quality measures of aggregated PRO data reported through a PROM and potentially used for performance assessment. In support of this goal, the HIQR now includes a THA/TKA PRO performance measure (PRO–PM), which

was developed using the PRO data voluntarily submitted under the original CJR Model. Therefore, CJR–X would use THA/TKA PRO–PM data submitted to the HIQR for the purpose of scoring model performance.

Second, CJR–X would adopt two additional measures to account for the high percentage of hospital outpatient LEJRs procedures. Outpatient same-day surgery has become commonplace in the United States. Nearly 70 percent of all surgeries are now performed in the outpatient setting. In fact, by the end of the CJR Model, outpatient procedures accounted for nearly three in four THA and TKA episodes. For this reason, we believe it necessary to supplement the previous measure set to include metrics which capture complications and patient experience related to outpatient surgery. Therefore, we propose to use additional quality measures that are currently reported under the Hospital Outpatient Quality Reporting (HOQR) Program (section 1833(t)(17)(C) of the Act).

The proposed measures would be used to determine hospital quality of care in the form of a composite quality score (CQS), as described in section X.C.2.e.(5). of this proposed rule. As observed in the 7th annual evaluation of the CJR model, the proportion of hospitals achieving "Good" or "Excellent" quality ratings has increased over the course of the CJR Model.<sup>469</sup> However, there is continued opportunity for quality improvement. Similar to the CJR Model, the CQS would be used to adjust the discount factor, as described in section X.C.2.f.(3)(g). of this proposed rule, that is applied to the CJR–X participants' reconciliation target price, as specified in section X.C.2.f.(5)(e). of this proposed rule, during the reconciliation process to tie quality performance to payment.

The measures we propose are as follows:

- Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).
- Hospital Visits Within 7 days of Hospital Outpatient Department (HOPD) Surgery.
- Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS).
- Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey (OAS CAHPS).

<sup>469</sup> *Comprehensive Care for Joint Replacement Model—Seventh Annual Report, December 3, 2025.* <https://www.cms.gov/priorities/innovation/innovation-models/cjr>.

- Hospital-Level Total Hip and/or Knee Arthroplasty (THA/TKA) Patient Reported Outcome (PRO)-Based Performance Measure.

We believe the CJR–X proposed measure set would provide CMS with sufficient information to monitor quality performance related to care provided to beneficiaries undergoing a hip or knee replacement and for the purposes of model evaluation. However, should we determine the need to adjust the measure set in future performance years, we would propose any changes through notice and comment rulemaking.

We seek comment on additional measures that should be considered for CJR–X.

### (3) Proposed Quality Measures

#### (a) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (CMIT ID #350)

THA and TKA are commonly performed procedures for the Medicare population that improve quality of life and are generally considered safe. However, as discussed in the 2015 CJR final rule (80 FR 73473 through 73477), post-operative complications related to these procedures do exist. The hospital-level risk-standardized complication rate (RSCR) following elective primary THA and/or TKA, also referred to as the THA/TKA Complications measure, was finalized for use in the CJR Model to measure a hospital's rate of mortality, myocardial infarction, pneumonia, sepsis, pulmonary embolism, bleeding, infection, and mechanical failure following inpatient surgery.<sup>470 471</sup>

The goal of this measure is to improve patient outcomes by providing patients, physicians, hospitals, and policy makers with information about complication rates following inpatient primary elective THA and/or TKA at a given hospital. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. Complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient

<sup>470</sup> "Primary" refers to an initial joint replacement. The measure does not assess revision joint replacement procedures.

<sup>471</sup> Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA), Centers for Medicare & Medicaid Services Measures Inventory Tool, CMIT Measure ID 350. <https://cmits.cms.gov/cmits/FamilyView?familyid=350>.

environment, all contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk-adjust for patient conditions at the time of hospital admission and then evaluate patient outcomes. The measure was developed to identify institutions whose performance is better or worse than would be expected based on their patient case mix, promote quality improvement, and better inform consumers about care quality.

The THA/TKA Complications measure captures the most common complications following inpatient THA and TKA. The outcome (complication) is defined as any one of the specified complications (not already present on admission) that occurs from the date of admission to 90 days following admission. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a “yes”: acute myocardial infarction (AMI), pneumonia or other acute respiratory complication, or sepsis/septicemia/shock during the index admission or within seven days of the start of the index admission; surgical site bleeding or other surgical site complication, pulmonary embolism, or death during the index admission or within 30 days of the start of the index admission; mechanical complication or periprosthetic joint infection/wound infection or other wound complication during the index admission or within 90 days of the start of the index admission.<sup>472</sup>

In the 2015 CJR final rule (80 FR 73473 through 73477), we described our reasoning for adopting the THA/TKA Complications measure. We shared historical information about the development of the measure, its implementation in CMS programs, and its public display. Our rationale for its continued use is unchanged. Given the

clinical alignment with the LEJR episode and its use in the CJR Model, the measure is well established and minimizes complexity since it is familiar to hospitals. Further, the measure reflects the full episode of care, and, given it is risk-standardized, reduces the incentive to avoid higher-risk patients. We believe this measure is beneficially actionable, at both the hospital and care team level, to influence performance through preoperative optimization, standardizing perioperative protocols, and incorporating post-acute care coordination and early complication management.

Therefore, we propose at § 512.635(a)(1) to use hospital-level RSCR following elective inpatient primary THA and/or TKA (CMIT ID #350) to assess episode quality performance starting in PY1 of CJR-X. We seek comment on the inclusion of this measure in the CJR-X measure set.

(b) Hospital Visits Within 7 Days of Hospital Outpatient Department (HOPD) Surgery (CMIT ID #344, OP-36)

There are well-described and potentially preventable adverse events that occur after outpatient surgery, such as uncontrolled pain, urinary retention, infection, bleeding, and venous thromboembolism, which can result in unexpected hospital visits. Similarly, non-clinical patient considerations, such as lack of transport home upon discharge and delayed start of surgery, are primary causes of unanticipated yet preventable hospital admissions following same-day surgery.

National estimates of hospital visit rates following surgery vary from 0.5 to 9.0 percent based on the type of surgery, outcome measured (admissions alone or admissions and emergency department visits), and timeframe for measurement after surgery. Additionally, these rates may vary among HOPDs, suggesting variation in surgical and discharge care quality. Therefore, using a quality measure of hospital visits following outpatient same-day surgery can improve transparency, inform patients and providers, and foster quality improvement.<sup>473</sup>

The Hospital Visits within 7 days of Hospital Outpatient Department (HOPD) Surgery measure assesses quality of care following surgery or cystoscopy performed in the hospital outpatient setting for Medicare beneficiaries. The measure outcome is any of the following

hospital visits: (1) an inpatient admission directly after the surgery; or (2) an unplanned hospital visit (inpatient admission, observation stay, or emergency department visit) occurring after discharge or within 7 days of the surgery. The measure score is a ratio of the predicted to expected number of post-surgical hospital visits among the HOPD's patients. The denominator is the expected number of hospital visits given the HOPD's case mix and surgical procedure mix. The numerator is the number of hospital visits predicted for the HOPD's patients accounting for its observed rate, the number of surgeries performed at the HOPD, the case mix, and the surgical procedure mix. A score of less than one indicates the HOPD's patients were estimated as having fewer post-surgical visits than expected compared to HOPDs with similar surgical procedures and patients. A ratio of greater than one indicates the HOPD's patients were estimated as having more visits than expected.

Although it is not specific to outpatient LEJRs, we believe the Hospital Visits within 7 Days of HOPD Surgery measure is an appropriate quality measure for inclusion in CJR-X model because it captures early, unplanned hospital utilization following outpatient surgical procedures, including elective total hip and total knee arthroplasty. It assesses complications similar to several of those included in the THA/TKA Complications measure and, for that reason, is a good complement to the original CJR inpatient measure. As joint replacement care is primarily furnished in outpatient settings, we believe this measure would help ensure that quality accountability under CJR-X reflects current clinical practice across care settings. The measure assesses early post-operative safety and care coordination by identifying emergency department visits, observation stays, and unplanned inpatient admissions shortly after discharge—events that are often associated with potentially preventable complications or gaps in discharge planning and post-operative support. We believe performance on this measure is actionable for hospitals and clinicians and complements the existing CJR-X inpatient complications measure in supporting the model's goals of improving quality, enhancing patient safety, and reducing avoidable episode spending.

We propose at § 512.635(a)(2) to use the Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36) measure to assess outpatient episode quality performance starting in PY1 of

<sup>472</sup> Exception: Subsequent inpatient admissions with a principal diagnosis code of COVID-19 (U07.1) or with a secondary diagnosis code of COVID-19 coded as present on admission on the claim within the seven/30-day time frames are not eligible for use by the measure (and are excluded) in determining whether AMI, pneumonia or other acute respiratory complication, sepsis/septicemia/shock, or pulmonary embolism occurred. The code list used to define the “Mechanical Complication” outcome includes 26 codes that reflect fractures of the pelvis, femur, tibia or fibula, or other bone following insertion of an orthopedic implant as well as periprosthetic fractures around the internal prosthetic joint.

<sup>473</sup> National Coverage Analysis (NCA) Decision Memo CAG-00157R4. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=288>.

CJR–X. We seek comment on the inclusion of this measure in the CJR–X measure set.

(c) Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (CMIT ID #338)

The Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS) is a national, standardized, publicly-reported survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience.<sup>474</sup> Since 2008, HCAHPS has allowed valid comparisons to be made across hospitals locally, regionally, and nationally. Three broad goals have shaped HCAHPS. First, the standardized survey and implementation protocol produce data that allow objective and meaningful comparisons of hospitals on topics that are important to consumers. Second, public reporting of HCAHPS results creates new incentives for hospitals to improve quality of care. Third, public reporting enhances accountability in health care by increasing transparency. With these goals in mind, CMS and the HCAHPS Project Team have taken substantial steps to assure that the survey is credible, practical and actionable.

HCAHPS is a 32-item survey instrument that produces 11 publicly reported measures: 7 multi-item measures (communication with doctors, communication with nurses, restfulness of hospital environment, care coordination, responsiveness of hospital staff, communication about medicines, and discharge information); and 4 single-item measures (cleanliness of the hospital environment, information about symptoms, overall rating of the hospital, and recommendation of hospital). The FY 2025 IPPS/LTCH PPS final rule describes HCAHPS survey measure updates starting with January 2025 discharges.

The HCAHPS Survey asks recently discharged patients about aspects of their hospital experience that they are uniquely suited to address. The core of the survey contains 20 items that ask how often or whether patients experienced a critical aspect of hospital care, rather than whether they were satisfied with their care and two global questions about rating and recommending the hospital. Also included in the survey are three screener items that direct patients to relevant questions, five items to adjust

for the mix of patients across hospitals, and two items that support Congressionally-mandated reports. Hospitals may include additional questions after the core HCAHPS items. HCAHPS is administered to a random sample of adult inpatients between 2 to 42 days after discharge. Patients admitted in the medical, surgical and maternity care service lines are eligible for the survey; HCAHPS is not restricted to Medicare beneficiaries. Hospitals may use an approved survey vendor or collect their own HCAHPS data if approved by CMS to do so. HCAHPS can be implemented in six survey modes: mail, telephone, mail with telephone follow-up, web with mail follow-up, web with telephone follow-up, or web with mail and telephone follow-up, each of which requires multiple attempts to contact patients. Hospitals must survey patients throughout each month of the year. IPPS hospitals must achieve at least 300 completed surveys over four calendar quarters.<sup>475</sup>

We believe the HCAHPS survey (CMIT ID #338) is an appropriate quality measure for inclusion in CJR–X because it relies on patient-reported experiences of hospital care, including communication with providers, responsiveness of staff, and discharge information, which are critical to successful joint replacement episodes. We believe patient experience is particularly relevant in the context of episode-based payment models, as effective communication and care transitions are closely associated with adherence to post-acute care plans, rehabilitation participation, and reduced risk of avoidable utilization. Because HCAHPS is a standardized, nationally-validated survey, it allows for consistent comparison of hospital performance. Moreover, the current use of this measure in the HIQR removes the need for CJR–X to introduce additional reporting burden. Including this measure would help ensure that incentives under CJR–X continue to support patient-centered care and balance cost containment with accountability for quality and beneficiary experience.

For the reasons specified previously, we propose at § 512.635(a)(3) to use the HCAHPS (CMIT ID #338) survey to assess inpatient episode quality performance starting in PY1 of CJR–X. We seek comment on the inclusion of this measure in the CJR–X measure set.

(d) Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey (OAS CAHPS) (CMIT ID #162)

The OAS CAHPS is the complement to the HCAHPS used for inpatient episodes. The OAS CAHPS survey collects feedback on patients' experiences or care in Medicare-certified HOPDs and ambulatory surgery centers (ASCs).<sup>476</sup> Though the surveyed population is all adults rather than solely Medicare beneficiaries, it still provides relevant information about the quality of care provided at a particular facility. Survey questions include questions about patients' experiences with their preparation for the surgery or procedure, check-in processes, cleanliness of the facility, communications with the facility staff, discharge from the facility, and preparation for recovering at home. The survey also includes questions about whether patients received information about what to do if they had possible side-effects during their recovery.<sup>477</sup> Outcomes are proportions of patients in HOPDs or ASCs that responded "Yes" to survey questions.

We believe the OAS CAHPS survey is an appropriate quality measure for inclusion in CJR–X because it captures beneficiaries' experiences with care in outpatient surgery settings, which are the primary setting for elective total hip and total knee arthroplasty. The inclusion of this measure would ensure that patient experience accountability is measured under CJR–X, regardless of setting. The survey assesses key domains such as communication with providers, information provided before and after surgery, pain management, and care coordination, all of which are critical to safe recovery and successful post-operative outcomes. OAS CAHPS is a standardized, nationally developed instrument that allows for consistent comparison of performance and its inclusion supports CJR–X's goals of promoting patient-centered care, care coordination, and high-quality outcomes across the episode.

We considered but did not propose the Patient Understanding of Key Information Related to Recovery After a

<sup>476</sup> Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under Consideration (MUC) List. Available at: <https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx><https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx>

<sup>477</sup> Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: <https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf><https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf>

<sup>474</sup> Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS), Centers for Medicare & Medicaid Services Measures Inventory Tool, CMIT Measure ID 338. <https://cmit.cms.gov/cmit/#/FamilyView?familyId=338>.

<sup>475</sup> For full details, see the current HCAHPS Quality Assurance Guidelines, V.19.0, under the Quality Assurance button on the official HCAHPS On-Line website at <https://www.hcahpsonline.org/en/quality-assurance/>.



Facility-Based Outpatient Procedure or Surgery PRO-PM (OP-46), rather than the OAS CAHPS for outpatient LEJR episodes.<sup>478</sup> The measure, also referred to as the Information Transfer PRO-PM, aims to assess the level of clear, personalized recovery information provided to patients who had surgery or a procedure at an HOPD. It reports the average score of a patient's ratings on a three-domain, 9-item survey to evaluate the clarity of the clinical information patients are given before, during, and after an outpatient surgery or procedure. While reporting to the HOQR is voluntary for procedures in CY 2026 (CY 2028 payment determination), the Information Transfer PRO-PM will be mandatory beginning with the CY 2027 reporting period (CY 2029 payment determination).<sup>479</sup>

This measure was also considered because it is used in TEAM and, as we have previously stated, we attempted, where feasible, to align CJR-X policies with TEAM to ensure a more reliable and valid comparison between the two models. Moreover, for reasons previously discussed, we strive to use PROs wherever possible to ensure patient voice is appropriately reflected in assessing quality of care. However, as a new measure, there is insufficient data available to reasonably estimate how CJR-X participants might perform on the Information Transfer PRO-PM. Because the CMS Chief Actuary requires a high level of certainty for estimating participant performance in order to certify a model for expansion, we were limited to established measures with sufficient historical data available for analysis. Until adequate data for the Information Transfer PRO-PM is available (which could potentially be attained through TEAM evaluations), we will use the OAS CAHPS measure. Should we propose to utilize the Information Transfer PRO-PM in the future, we would propose such a change through notice and comment rulemaking.

Therefore, we propose at § 512.635(a)(4) to use the OAS CAHPS (CMIT #162, OP-46) to assess outpatient episode quality performance starting in PY1 of CJR-X. We seek comment on the inclusion of this measure in the CJR-X measure set.

<sup>478</sup> Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (PRO-PM), Version 1.0 Methodology Report, April 2024. <https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf>.

<sup>479</sup> Hospital Outpatient Quality Reporting (OQR) Program Measures. <https://qualitynet.cms.gov/2outpatient/oqr/measures>.

(e) Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618)

Administrative claims-based THA/TKA Complications and hospital readmission measures have been publicly reported since 2013. However, neither of these measures capture the reasons for which patients undergo elective THA and TKA (for example, Will quality of life be improved after undergoing the procedure?). Therefore, a quality measure based upon PRO data provides both patients and providers with a unique and critical perspective on care.

As the goal of the procedures is to improve quality of life, THA and TKA are ideal candidates for assessing PROs. The original CJR model included voluntary reporting of PRO data. In order to meet the requirements for successful submission of PRO data, hospitals had to submit the Veterans RAND 12 Item Health Survey (VR-12) or Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 generic PRO survey; and the (HOOS Jr.)/(KOOS Jr.) or HOOS/KOOS subscales PRO survey for patients undergoing eligible elective primary THA/TKA procedures.

Using the data collected from CJR participants, CMS developed the THA/TKA PRO-PM (CMIT ID #1618) to assess the quality of care delivered to Medicare beneficiaries undergoing elective THA or TKA.<sup>480</sup> As described in the FY 2023 IPPS/LTCH PPS Final rule (87 FR 48780), the THA/TKA PRO-PM would be a mandatory requirement for hospitals included in the Hospital IQR Program beginning July 1, 2025. Therefore, voluntary PRO submission is no longer a relevant incentive. Rather, its inclusion in the HIQR provides an opportunity for CJR-X to access this data without additional burden to CJR-X participants.

The Hospital-Level THA/TKA PRO-PM measure is an appropriate quality measure for inclusion in CJR-X because it directly assesses improvements in patients' pain, physical function, and health-related quality of life following elective joint replacement. Unlike utilization- or complication-based measures, this measure captures outcomes that matter most to beneficiaries and reflects the primary

<sup>480</sup> Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure, Centers for Medicare & Medicaid Services Measures Inventory Tool, CMIT Measure ID 1618. <https://cmits.cms.gov/cmits/#/FamilyView?familyId=1618>.

clinical goal of total hip and knee arthroplasty. The measure evaluates change in patient-reported outcomes from before surgery to after recovery, which provides a meaningful assessment of episode-level effectiveness and complements existing CJR-X quality measures. In addition, because the measure is risk-adjusted and allows for fair comparison across hospitals, it would support accountability while minimizing incentives to avoid higher-risk patients. Including this measure would strengthen alignment between the CJR-X financial incentives and patient-centered care and support the model's goals of improving quality, value, and beneficiary experience across the episode of care.

As stated, THA/TKA PRO-PM reporting is currently only mandatory in the HIQR. However, we believe the inpatient measure provides an overall reflection of hospital performance related to LEJR care and can appropriately be used to infer quality of care for outpatient episodes even in the absence of outpatient-specific PRO collection. Therefore, we do not propose to require PRO submission for outpatient CJR-X episodes but will use the inpatient THA/TK PRO-PM to assess quality of care for all LEJR episodes, regardless of setting.

We note that voluntary THA/TKA PRO reporting to the HOQR (OP-42) has already begun for procedures performed in CY 2025 and mandatory reporting will begin for procedures performed in CY 2028 (2031 payment determination).<sup>481</sup> CJR-X may rely on data from the HOQR when it becomes available, but would propose such a change through CJR-X notice and comment rulemaking.

Therefore, we propose at § 512.635(a)(5) to use the Hospital-Level THA/TKA PRO-PM (CMIT ID #1618) to assess inpatient and outpatient LEJR episode quality performance starting in PY1 of CJR-X. We seek comment on the inclusion of this measure in the CJR-X measure set and alternatives to our proposal to apply the PRO-PM to outpatient episodes.

#### (4) Quality Measure Reporting

##### (a) Display of Quality Measures and Performance Periods

We believe that the display of measure results is an important way to educate the public on hospital performance and increase the transparency of the model. We propose

<sup>481</sup> Patient-Reported Outcome Performance Measures Overview, CMS QualityNet. <https://qualitynet.cms.gov/outpatient/measures/PRO-PM>.



at § 512.635(f) to display quality measure results on the publicly available CMS website in a form and manner consistent with other publicly reported measures. CMS would share each CJR-X participants' quality metrics with the hospital prior to display on the CMS website. The timeframe for when CJR-X participants would receive data on our proposed measures aligns with the Care Compare schedule that can be found here: <https://data.cms.gov/provider-data/topics/hospitals/measures-and-current-data-collection-periods>. All measures under the statutory hospital quality programs have a 30-day preview period prior to results being posted on the Care Compare web page. CJR-X participant measure scores would be delivered to CJR-X

participants confidentially. We propose to publicly report PY 1 measure scores in calendar year 2029 and we would continue to publicly report scores every performance year with an approximate 1-year lag. We believe this approximate 1-year lag period is a sufficient amount of time to ensure accuracy of the measures data.

We also recognize that measure performance periods would not align perfectly with performance years based on availability of data needed to assess quality performance in CJR-X. We propose the following measure performance periods, summarized in Table X.C.-01. While only 5 performance years are displayed in the table, we are proposing that the measure performance periods would continue at

the same cadence each performance year. Where possible, these proposed measure performance periods align with existing CMS quality reporting program measure performance periods to minimize CJR-X participant confusion. We also acknowledge that the measure performance periods do not exactly line up with the performance years used in CJR-X. While this creates some disparity between measure performance periods and model performance years, we believe this approach is the least burdensome to CJR-X participants because it does not require them to report on these measures separately for CJR-X. Additionally, this approach is similar to how some measures were captured in the original CJR model as well as TEAM.

**TABLE X.C-01: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR IN CJR-X**

| Quality Measure                                                              | CJR-X Performance Year (PY)        |                                    |                                   |                                   |                                   |
|------------------------------------------------------------------------------|------------------------------------|------------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
|                                                                              | PY1                                | PY2                                | PY3                               | PY4                               | PY5                               |
| Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350) | April 1, 2026- March 31, 2028      | April 1, 2027- March 31, 2029      | April 1, 2028- March 31, 2030     | April 1, 2029- March 31, 2031     | April 1, 2030- March 31, 2032     |
| Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36)          | January 1, 2027- December 31, 2027 | January 1, 2028- December 31, 2028 | January 1, 2029-December 31, 2029 | January 1, 2030-December 31, 2030 | January 1, 2031-December 31, 2031 |
| HCAHPS Survey (CMIT ID #338)                                                 | January 1, 2027- December 31, 2027 | January 1, 2028- December 31, 2028 | January 1, 2029-December 31, 2029 | January 1, 2030-December 31, 2030 | January 1, 2031-December 31, 2031 |
| OAS CAHPS Survey (CMIT ID #162)                                              | January 1, 2027- December 31, 2027 | January 1, 2028- December 31, 2028 | January 1, 2029-December 31, 2029 | January 1, 2030-December 31, 2030 | January 1, 2031-December 31, 2031 |
| Hospital-Level THA/TKA PRO-PM (CMIT ID #1618)                                | July 1, 2026-June 30, 2027         | July 1, 2027-June 30, 2028         | July 1, 2028- June 30, 2029       | July 1, 2029- June 30, 2030       | July 1, 2030- June 30, 2031       |

We seek comment on our proposals at § 512.635(e) on how quality measures in CJR-X would be displayed and the quality measure performance periods.

#### (b) Data Submission Criteria

We believe it is important to be transparent and to outline the form, manner, and timing of quality measure data submission so that accurate measure results are provided to hospitals, and that timely and accurate calculation of measure results are consistently produced to determine reconciliation payment amounts and repayment amounts. We propose that data submission for the Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350), the HCAHPS survey (CMIT ID #338), and the Hospital-Level THA/TKA PRO-PM (CMIT #1618) would be accomplished through existing Hospital Inpatient Quality Reporting Program processes. Since these measures are reported to the Hospital IQR or other CMS quality

reporting programs, CJR-X participants would not need to submit additional data for CJR-X.

For measures in the outpatient setting, we propose that data submission for the Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36) and the OAS CAHPS (CMIT #162) survey be accomplished through the existing Hospital Outpatient Quality Reporting Program. Therefore, CJR-X participants would not need to submit additional data for CJR-X.

#### (5) Composite Quality Score (CQS)

##### (a) Overview

We believe that the proposed CJR-X provides another mechanism for CJR-X participants to improve quality of care, while also achieving cost efficiency. Incentivizing high-value care through episode payments for LEJR is a primary objective of the model. Therefore, incorporating quality performance into the episode payment structure is an essential component of CJR-X, just as it

was for the CJR Model (80 FR 73370) and for TEAM (89 FR 69774). We believe it is important for CJR-X to link the financial reward opportunity with performance in the quality of care for Medicare beneficiaries in a LEJR episode.

As discussed in section X.C.2.f. of this proposed rule, which outlines the pricing methodologies for CJR-X, we propose setting a target price for LEJR episodes. We would apply the CJR-X participant's discount factor, based on the participant's quality performance for the performance year, to calculate the reconciliation target price for LEJR episodes. We refer to section X.C.2.f.(5)(e). of this proposed rule for further discussion of the relationship between a CJR-X participant's quality performance and the discount factor. A CJR-X reconciliation target price would represent expected spending on all related Part A and Part B items and services furnished during a LEJR episodes and would incorporate the

CJR–X participant’s discount factor for the performance year. CJR–X participants that achieve actual FFS spending below the reconciliation target price for a given performance year may be eligible for a reconciliation payment from CMS, subject to the proposed stop-gain limit policy as discussed in section X.C.2.f.(5)(g), of this proposed rule. CJR–X participants that achieve actual FFS spending that exceed the reconciliation target price for a given performance year would be required to pay CMS a repayment amount, subject to the stop-loss limit policy as discussed in section X.C.2.f.(5)(g), of this proposed rule.

We propose a composite quality score methodology for linking quality and payment in CJR–X that is similar to, but not the same, as the methodology that was finalized for the CJR Model (80 FR 73363 through 73381). We propose to define the “composite quality score” at § 512.605 as a score computed for each CJR–X participant to summarize the CJR–X participant’s level of quality performance on specified quality measures as described in § 512.635. Notably different is the inclusion of outpatient quality measures in CJR–X and thus the assessment of these measures in the composite quality score. The CJR–X composite quality score methodology would allow performance on each required quality measure to be meaningfully valued in the CJR–X’s pay-for-performance methodology, incentivizing and rewarding cost savings in relation to the quality of episode care provided by the CJR–X participant.

Although performance on each measure would be valued in the CJR–X composite quality score methodology, it is the CJR–X participant’s overall quality performance under the CJR–X that would be considered in the pay-for-performance approach, rather than performance on each quality measure individually determining the financial opportunity under CJR–X. The composite score methodology also provides a framework for incorporating additional measures of meaningful outcomes in the future. Finally, while we believe that high performance on all of the quality measures represents goals of clinical care that should be achievable by all CJR–X participants that heighten their focus on these measures, we appreciate that many CJR–X participants would have room for significant improvement in their current measure performance. The composite score methodology would provide the potential for financial reward for CJR–X participants that reach “good” or “excellent” quality performance, thus incentivizing their continued efforts to improve the quality and efficiency of LEJR episodes.

#### (b) Determining Quality Measure Performance

We believe that assessing measure performance by comparing CJR–X participants against a national distribution for the proposed CJR–X measures would be the most appropriate way to incorporate quality performance into CJR–X. Moreover, we believe that hospitals nationally are currently

working to improve their performance on quality measures on an ongoing basis as some of these measures are included in other CMS programs such as the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs. Therefore, we expect that CJR–X participants would have a heightened focus on performance on these measures as a result of the financial incentives resulting from the CJR–X payment methodology.

Thus, at the time of reconciliation for a performance year, we propose at § 512.635(c) to assign each CJR–X participant’s measure point estimate from the measure performance period, as discussed in section X.C.2.e.(5)(d), of this proposed rule, to a performance percentile based on the national distribution of measure results for hospitals that are eligible for payment under the IPPS reporting the measure, as discussed in section X.C.2.e.(5)(d), of this proposed rule, that meets the minimum patient case or survey count. This proposal applies to the Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350); the Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP–36); the HCAHPS Survey (CMIT ID #338); the OAS CAHPS Survey (CMIT #162); and the Hospital-Level THA/TKA PRO–PM (CMIT #1618). The measure-specific parameters for minimum case/survey count that would apply to developing the national distributions are displayed in Table X.C–02.

**TABLE X.C-02: MINIMUM REQUIREMENTS FOR USE IN NATIONAL DISTRIBUTION**

| Measure                                                                      | Requirements for use in national distribution                     |
|------------------------------------------------------------------------------|-------------------------------------------------------------------|
| Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350) | At least 25 patient cases in the measure performance period.      |
| Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36)          | At least 25 patient cases in the measure performance period.      |
| HCAHPS Survey (CMIT ID #338)                                                 | At least 100 completed surveys in the measure performance period. |
| OAS CAHPS Survey (CMIT ID #162)                                              | At least 100 completed surveys in the measure performance period. |
| Hospital-Level THA/TKA PRO-PM (CMIT ID #1618)                                | At least 25 patient cases in the measure performance period.      |

We propose at § 512.635(d) to assign any CJR–X participant without a reportable value for the measure, new hospitals that are identified as CJR–X participants, or CJR–X participants where CMS has suppressed the measure value due to an error in the data used to calculate the measure to the 50th performance percentile of the measure result, so as not to disadvantage a CJR–X participant based on its lack of applicable cases because that CJR–X participant may in actuality provide high quality care. We believe that

relative measures of quality performance are most appropriate for CJR–X as hospitals continue to make progress nationally on improving patient outcomes and experience. This approach is also consistent with the CJR Model.

We seek comment on our proposals at §§ 512.635(c) and (d) to determine quality measure performance based on assigning the CJR–X participant’s measure point estimate to a measure performance percentile based on the national distribution of measure results

from hospitals eligible for payment under the IPPS.

#### (c) Quality Improvement

We recognize the CJR Model rewarded CJR participant hospitals for quality improvement, similar to the pay-for-performance policies under other programs such as the Hospital Value-Based Purchasing Program, in order to provide an incentive for quality improvement for CJR participant hospitals at all levels of quality performance (70 FR 73379). As in the CJR Model, we believe the heightened

focus on episode spend and quality performance by CJR–X participants may lead to substantial year-over-year quality measure improvement. Nevertheless, we believe that the actual level of quality performance achieved in CJR–X should be most highly valued in the composite quality score to reward those CJR–X participants furnishing high-quality care to CJR–X beneficiaries.

We considered, but are not proposing, to include a policy that provides CJR–X participants quality improvement points when there is improvement of 2 deciles or more in comparison to the national distribution of measure results from the prior year, based on a comparison of relative quality measure performance over the most recent 2 years of available quality measure result data. CJR–X participants who are able to demonstrate quality improvement, could be awarded 10 percent of the maximum measure performance score, with a cap for the overall composite quality score at 20 points. This is the same methodology as was used in the CJR Model.

However, we are not proposing to include quality improvement points in CJR–X because we believe CJR–X is structured to emphasize absolute quality performance on clinically meaningful outcomes, rather than short-term year-over-year changes that may reflect random variation or changes in case mix. Further, we believe focusing on achievement-based performance promotes consistent accountability for patient safety, experience, and outcomes across CJR–X participant hospitals.

In addition, CJR–X already provides incentives for improvement through its financial reconciliation structure, as hospitals can benefit from lower episode spending while maintaining quality thresholds. Excluding improvement points also supports transparency and predictability in quality scoring, allowing hospitals to better understand how quality performance affects reconciliation payments and to invest in sustained, long-term care redesign strategies. Lastly, this approach aligns with TEAM as quality improvement points are not included in the model’s composite quality score calculation. Thus, we believe not including quality improvement points aligns with the goals of the model by balancing fairness, administrative simplicity, and accountability for high-quality, patient-centered care.

We seek comment on not including a policy for quality measure improvement for CJR–X.

(d) Calculating the Composite Quality Score

We propose adopting a similar calculation of the CJR Model composite quality but with modifications to account for outpatient quality measures. The CJR Model CQS was constructed based on the performance of two inpatient quality measures and one voluntary inpatient measure. The measures were weighted 50 percent for the complications measure, 40 percent for patient experience measure, and 10 percent for the patient reported outcomes measure with the sum of quality points capped at 20 points. Given the greater proportion of episodes initiating in the outpatient setting, CJR–X has proposed adopting two outpatient quality measures to capture quality performance for episodes in the outpatient setting. The CJR–X CQS methodology would account for these two measures by constructing an outpatient measure composite quality score that mimics the CJR Model weighting and quality point cap. Specifically, we propose placing each of the five proposed quality measures, as described in section X.C.2.g. of this proposed rule, into one of three quality domains. The domains would be complications, patient experience, and patient reported outcomes. We propose for inpatient measures and outpatient measures to weight the complications domain at 50 percent, the patient experience domain at 40 percent, and the patient reported outcomes domain at 10 percent. We believe the approach to weighting the quality domains represents a balanced and equitable approach to assessing hospital performance under CJR–X and aligns with the CJR Model. The complications quality domain would be weighted most heavily because it reflects serious, clinically significant outcomes that directly affect patient safety, recovery, and episode spending, and are supported by mature, well-validated, claims-based measures. Patient experience measures receive substantial weight because effective communication, discharge planning, pain management, and care coordination are critical drivers of post-acute utilization and successful recovery in joint replacement episodes. Lastly, patient-reported outcome measures are included to capture improvements in pain and function that matter most to beneficiaries, while being weighted more modestly to reflect ongoing considerations related to response rates, data completeness, and measure stability. Together, this weighting approach promotes accountability for safety and outcomes while ensuring that patient-centered perspectives meaningfully inform quality performance, supporting a fair, reliable, and comprehensive assessment aligned with the goals of CJR–X. Table X.C–03 displays the proposed quality measures and associated quality domain weights.

**TABLE X.C-03: MEASURES AND PROPOSED QUALITY DOMAIN WEIGHTS FOR THE COMPOSITE QUALITY SCORE**

| Quality Domain            | Quality Measures                                                             |                                                                     | Domain Weight in Composite Quality Score |
|---------------------------|------------------------------------------------------------------------------|---------------------------------------------------------------------|------------------------------------------|
|                           | Inpatient Measure                                                            | Outpatient Measure                                                  |                                          |
| Complications             | Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350) |                                                                     | 50%                                      |
|                           |                                                                              | Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36) |                                          |
| Patient Experience        | HCAHPS Survey (CMIT ID #338)                                                 |                                                                     | 40%                                      |
|                           |                                                                              | OAS CAHPS Survey (CMIT ID #162)                                     |                                          |
| Patient Reported Outcomes | Hospital-Level THA/TKA PRO-PM (CMIT ID #1618)                                |                                                                     | 10%                                      |

Under this approach, we propose we would score each CJR–X model participant on the five proposed quality measures based on the CJR–X participant’s performance percentile as compared to the national distribution of hospitals that are eligible for payment under the IPPS measure performance, assigning points according to the

proposed point values displayed in Table X.C-04.

**TABLE X.C-04: POINT VALUES FOR PROPOSED CJR-X QUALITY MEASURES**

| Performance Percentile                  | Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350) | Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36) | HCAHPS Survey (CMIT ID #338) | OAS CAHPS Survey (CMIT ID #162) | Hospital-Level THA/TKA PRO-PM (CMIT ID #1618) |
|-----------------------------------------|------------------------------------------------------------------------------|---------------------------------------------------------------------|------------------------------|---------------------------------|-----------------------------------------------|
| >90 <sup>th</sup>                       | 10.00                                                                        | 10.00                                                               | 8.00                         | 8.00                            | 2.00                                          |
| ≥80 <sup>th</sup> and <90 <sup>th</sup> | 9.25                                                                         | 9.25                                                                | 7.40                         | 7.40                            | 1.85                                          |
| ≥70 <sup>th</sup> and <80 <sup>th</sup> | 8.50                                                                         | 8.50                                                                | 6.80                         | 6.80                            | 1.70                                          |
| ≥60 <sup>th</sup> and <70 <sup>th</sup> | 7.75                                                                         | 7.75                                                                | 6.20                         | 6.20                            | 1.55                                          |
| ≥50 <sup>th</sup> and <60 <sup>th</sup> | 7.00                                                                         | 7.00                                                                | 5.60                         | 5.60                            | 1.40                                          |
| ≥40 <sup>th</sup> and <50 <sup>th</sup> | 6.25                                                                         | 6.25                                                                | 5.00                         | 5.00                            | 1.25                                          |
| ≥30 <sup>th</sup> and <40 <sup>th</sup> | 5.50                                                                         | 5.50                                                                | 5.40                         | 5.40                            | 1.10                                          |
| <30 <sup>th</sup>                       | 0.00                                                                         | 0.00                                                                | 0.00                         | 0.00                            | 0.00                                          |

We believe that small point increments related to higher measure performance deciles would be the most appropriate way to assign more points to reflect meaningfully higher quality performance on the measures. The absolute differences for each decile among the five measures reflect the intended weight of the measure in the composite quality score.

After determining the point value for each measure, we propose summing the performance points for the inpatient measures to construct the inpatient measure composite quality score and sum the outpatient measures to construct the outpatient measure composite quality score. We propose at § 512.605 to define the “inpatient measure composite quality score” as the sum of inpatient quality measure point values capped at 20 points. Likewise, we propose at § 512.605 to define the “outpatient composite quality score” as the sum of outpatient quality measure point values, capped at 20 points.

We propose to assign each CJR-X participant an “overall composite quality score,” defined at § 512.605 as the sum of the weighted average of the inpatient measure composite quality score and the outpatient measure composite quality score, capped at 20 points. The inpatient and outpatient composite quality score would be weighted based on the proportion of inpatient to outpatient episodes. For example, if a CJR-X participant with 90 percent outpatient episode volume earned a 17.00 on their inpatient composite quality score and a 14.00 on their outpatient composite quality score, then their overall composite quality score would be calculated as follows:

- Inpatient measure composite quality score = 17.00.
- Outpatient measure composite quality score = 14.00.
- Inpatient/outpatient episode volume proportion—
  - ++ 10 percent inpatient; and
  - ++ 90 percent outpatient.
- Overall composite quality score =  $((0.10) \times (17.00)) + ((0.90) \times (14.00)) = 14.3$ .

We believe the proposed composite quality score methodology for CJR-X is a sound approach because it combines multiple, complementary quality measures into a single assessment of hospital performance across the episode of care, reflecting the multidimensional nature of quality in joint replacement. By incorporating measures of patient safety, patient experience, and patient-reported outcomes, the composite score avoids over-reliance on any single metric and improves the reliability and stability of quality assessment by mitigating the effects of random variation in individual measures. The methodology recognizes quality achievement and incentivizes meaningful progress across all CJR-X participants. This standardized and transparent approach promotes equitable comparisons across CJR-X participants, enhances predictability in reconciliation outcomes, and aligns financial incentives with the patient-centered quality goals of the model.

The proposal for the methodology to calculate the composite quality score is included in § 512.635(b)(1) and (2). We seek comment on our proposed methodology to calculate the composite quality score and on our definitions for the composite quality scores at § 512.605.

#### f. Proposed Pricing and Payment Methodology

##### (1) Background

Given that we are proposing CJR-X as an expansion of the CJR Model, as opposed to a new model concept, our initial foundation for the pricing and payment methodology is the set of policies from the CJR Extension. As initially discussed in section X.C.1.b. of this proposed rule, we are proposing several, minor modifications for CJR-X that will align with some of the policies we enacted in TEAM, which we believe represented improvements to the CJR Model methodology.

As we developed the methodologies for the CJR and BPCI Advanced Models, and refined them over time in response to observed changes in nationwide spending trends and payment system changes (such as the removal of TKA and THA from the IPO list, and the reclassifications of certain MS-DRGs), each new iteration drew from lessons learned in the previous iteration. With TEAM, we aimed to find a balance between simplicity and predictive accuracy of target prices, blending and building upon methods from both the original CJR Model and BPCI Advanced Model. Our goal was to choose a payment methodology that was as transparent and understandable as possible for participants of varying levels of statistical background and knowledge, but robust and statistically sophisticated enough to accurately predict performance period spending.

For CJR-X, we aim to achieve a similar balance between simplicity and predictive accuracy, but with an added focus on long-term sustainability. As an expanded, national model, CJR-X is unique from the other models discussed

here in that it is not being proposed as a finite, model test that will occur over a relatively short period of time. Therefore, when evaluating the different approaches to pricing and payment that have been used in other models, both past and present, we must also consider how each approach would perform in the long-term. We believe that a pricing and payment methodology that is transparent, accurate, and adaptable to evolving payment and health care industry trends will be crucial for achieving our goals of improving quality and lowering costs over the long term.

It is also important to note that, whereas the goal for new (Phase I) models is to test and generate evidence on a novel payment policy design, the goal of model expansion (Phase II) is to take a payment policy design that has already proven effective and apply it to a larger scope of episodes. Thus, while we are proposing several minor adjustments to the CJR Model pricing and payment methodology, in order to improve upon the policies that were tested, we must adhere to the general design and structure that was tested in and for which we can confidently predict the long-term effects on both quality and spending.

#### (a) CJR Model Pricing Methodology

When designing the CJR Model payment methodology, some of the primary goals were simplicity and clarity, given that it was a mandatory model covering only one episode category. The original CJR Model payment methodology included a 3-year baseline period that rolled forward every 2 years. Target prices used a blend of participant-specific and regional spending, which shifted towards 100 percent regional spending for PYs 4 and 5. Downside risk was waived for the first performance year of the model to allow participants time to enact practice changes that would help them succeed in the model. Beginning in PY 2, participants were subject to both upside and downside risk, within stop-loss and stop-gain limits that increased to a maximum of 20 percent by PY 3 for most hospitals. The stop-loss and stop-gain limits were designed to ensure that participants would neither be subject to an unmanageable level of risk, nor be incentivized to stint on care to achieve savings. The original CJR Model payment methodology is described in detail in the 2015 CJR final rule, (*80 FR 73324* through *73554*).

The original CJR Model payment methodology was modified in the 2021 CJR 3-Year Extension final rule. The CJR Model's 3-year extension and modification was due to a number of

factors, as described in detail starting at *86 FR 23508*. A principal reason for the modifications to the payment methodology was the fact that the original CJR Model target price methodology did not account for changing downward trends in spending on LEJR episodes, both among CJR participant hospitals and non-participant hospitals. The resulting reconciliation payments under the initial methodology rewarded participants for spending reductions that likely would have happened regardless of the model, which led to concerns that target prices could be too high for Medicare to achieve savings in the model over time.

The changes to the model increased the complexity in some ways (for example, the addition of risk adjustment multipliers) while simplifying it in other ways (for example, the removal of update factors) in order to calculate target prices that would more accurately reflect performance period spending. A retrospective Market Trend Factor was applied to target prices at reconciliation to capture changes in spending patterns that occurred nationally during the performance period. This market trend factor, in combination with the change from a 3-year baseline to a 1-year baseline, negated the need for setting-specific update factors that we had used previously to set purely prospective target prices. At the same time, our added risk adjustment increased target prices for episodes with more complex patients, to better reflect the higher costs associated with those patients. The changes to the original CJR Model payment methodology are described in detail in the 2021 CJR 3-Year Extension final rule (*86 FR 23508*).

#### (b) TEAM Pricing Methodology

The TEAM methodology, as discussed in the FY 2025 IPPS/LTCH PPS final rule (*89 FR 69748*) and FY 2026 IPPS/LTCH PPS final rule (*90 FR 37092*), was designed with the goal of blending the most successful elements from the different CJR and BPCI Advanced Model iterations in order to strike a balance between predictability and accuracy. TEAM sets preliminary target prices at the MS-DRG/HCPCS episode type- and region-level using a 3-year baseline, trended forward to the performance year. Preliminary target prices are updated using the performance year data during the reconciliation process to account for updated spending trends (subject to a 3 percent cap) and normalization factor (subject to a 5 percent cap) and by adjusting for each participant's realized performance year case mix.

TEAM's risk adjustment includes adjusters for age group, Hierarchical Condition Category (HCC) count, and beneficiary economic risk, as well as episode category-specific HCC adjusters and hospital-level adjusters including a hospital bed size factor and a safety net hospital factor. The risk adjustment factors will be calculated at the MS-DRG/HCPCS level using a weighted linear regression where episodes are weighted differentially based on whether they belong to year 1, 2, or 3 of the baseline periods. After risk adjusting for the performance year case mix, target prices are normalized to ensure that the average of the total risk-adjusted preliminary target price does not exceed the average of the total non-risk adjusted preliminary target price.

TEAM participants will have the opportunity to achieve a reconciliation payment amount, after accounting for quality performance, if their performance year spending is below the reconciliation target price, or they may owe a repayment amount if their spending is above the reconciliation target price.

#### (2) Overview of Proposed CJR-X Pricing and Payment Methodology

While we describe each element of the pricing and payment methodology in detail in the following sections, here we present an overview of the proposed CJR-X pricing and payment methodology. At proposed \$ 512,640, we are proposing to use 3 years of baseline data, trended forward to the performance year, to calculate target prices at the level of MS-DRG/HCPCS episode type and region. We propose to group episodes from the baseline period by applicable MS-DRG for episode types that include only inpatient hospitalizations, and by applicable MS-DRG or HCPCS code for episode types that include both inpatient hospitalizations and outpatient procedures. For episode types that include both inpatient hospitalizations (identified by MS-DRGs) and outpatient procedures (identified by HCPCS codes), HCPCS codes are combined for purposes of target pricing with the applicable MS-DRG representing an inpatient hospitalization without Major Complications and Comorbidities, as we expect those beneficiaries to have similar clinical characteristics and costs. After capping high-cost outlier episodes at the 99th percentile for each of the 4 proposed MS-DRG/HCPCS episode types, we propose to use average standardized spending for each MS-DRG/HCPCS episode type in each region as the benchmark price for that MS-DRG/HCPCS episode type for that

specific region, resulting in 36 MS–DRG/HCPSC episode type/region-level benchmark prices. We propose to apply a prospective trend factor and a discount factor to benchmark prices (as well as a prospective normalization factor, described later in this section) to calculate preliminary target prices. The prospective trend factor would represent expected changes in overall spending patterns between the most recent calendar year of the baseline period and the performance year, based on observed changes in overall spending patterns between the earliest calendar year of the baseline period and the most recent year of the baseline period. The discount factor would represent Medicare's portion of potential savings from the episode. At proposed § 512.645(a), we propose to risk adjust episode-level target prices at reconciliation by facility bed-size and safety net status, as defined in § 512.605, along with the following beneficiary-level variables: age group, Hierarchical Condition Category count (a measure of clinical complexity), beneficiary economic risk (the components of which are described in more detail in section X.C.2.f.(4). of this proposed rule), prior post-acute care use, disability status as reason for initial Medicare enrollment, and recent medical history (represented as 22 separate, binary variables indicating relevant services or HCC flags during the 180-day lookback). We propose to calculate risk adjustment multipliers prospectively at the MS–DRG/HCPSC episode type level based on baseline data and hold those multipliers fixed for the performance year. To ensure that risk adjustment does not inflate target prices overall, we further propose to calculate a prospective normalization factor based on the data used to calculate the risk adjustment multipliers. We propose to apply the prospective normalization factor, in addition to the prospective trend factor and discount factor described previously, to the benchmark price to calculate the preliminary target price for each MS–DRG/HCPSC episode type and region. We propose that the prospective normalization factor would be subject to a limited adjustment at reconciliation based on CJR–X participants' observed performance period case mix, such that the final normalization factor would not exceed  $\pm 5$  percent of the prospective normalization factor. We would use standardized payment data to perform these target price calculations. A simplified equation for the construction of preliminary target prices would be—

$$\begin{aligned} \text{Preliminary Target Price} = & \text{Benchmark} \\ & \text{Price} * \text{Prospective Trend Factor} * \\ & \text{Prospective Normalization Factor} * \\ & \text{Risk Adjustment Multipliers} * \\ & \text{Discount Factor} \end{aligned}$$

We note that construction of the reconciliation target price, as discussed in section X.C.2.f.(5)(d). of this proposed rule, would account for realized patient case mix and spending trends and result in updates to the trend factor and normalization factors.

As described in detail in the following sections, many of the payment and pricing policies that we are proposing for CJR–X represent minor deviations from the policies that were tested in the original CJR Model and the CJR Extension. Many of the proposed policy adjustments are intended to align with specific policies enacted in TEAM, which we believed would improve upon the CJR Model methodology in a manner that was predictable and would not fundamentally alter the general structure of the model that was tested. As discussed in section X.C.2.f.(1)(c). of the proposed rule, TEAM was designed, in large part, based on the lessons that had been learned from the CJR Model test. It drew from the strongest elements of the CJR Model and improved upon the weaker elements. Given that TEAM launched on January 1, 2026, we have not yet evaluated the effectiveness of the TEAM policies versus the CJR Model policies, nor have we received any evidence to discredit the rationale for these policy improvements.

### (3) Target Prices

#### (a) Baseline Period for Benchmarking

We propose using 3 years of baseline episode spending to calculate benchmark prices, which we would further adjust as described in section X.C.2.f.(4). of this proposed rule to create preliminary target prices. Specifically, at § 512.605, we propose to define “baseline period” as the 3-year historical period used to construct the preliminary target price and reconciliation target price for a given performance year. We also propose to define “baseline episode spending” as total episode spending by all providers and suppliers associated with a given MS–DRG/HCPSC episode type for all hospitals in a given region during the baseline period. We propose to roll this 3-year baseline period forward every year. Specifically, we propose the following:

- To determine baseline episode spending for PY1, CMS would use baseline episode spending for episodes with anchor hospitalization start dates or anchor procedure dates beginning on

or after October 1, 2023 and anchor hospitalization discharge dates or anchor procedure dates between October 1, 2023 and September 30, 2026.

- To determine baseline episode spending for PY2 and future performance years, CMS would use same 3-year cadence to roll the baseline period forward a year.

- For example, to determine baseline episode spending in PY2, CMS would use baseline episode spending for episodes with anchor hospitalization start dates or anchor procedure dates beginning on or after October 1, 2024 and anchor hospitalization discharge dates or anchor procedure dates between October 1, 2024 and September 30, 2027.

The use of 3 years of baseline episode spending is consistent with our initial CJR methodology, as described in the 2015 CJR final rule (80 FR 73340). In that case, the 3-year baseline period moved forward every 2 years. However, in combination with the lack of a retrospective trend factor, the use of a 3-year baseline period that only moved forward every 2 years meant that our methodology was not able to capture the degree to which spending on LEJR episodes was decreasing nationwide, both among CJR and non-CJR hospitals. As a result, we believe our target prices partially reflected spending decreases that were not due specifically to participation in CJR.

Subsequently, in the 2021 CJR 3-Year Extension final rule, we finalized a policy to use a 1-year baseline period that would move forward every year (with the exception of skipping data from 2020 due to COVID–19 irregularities) (86 FR 23514). In combination with a retrospective market trend factor, using 1 year of baseline episode spending updated every year meant that our target prices would not be inflated as they had been under the initial CJR methodology. BPCI Advanced employs a strategy that blends elements of both CJR approaches, with a longer baseline period (4 years) similar to the initial CJR methodology, but shifting forward every year, as we do in the CJR extension.

Participants in episode-based payment models have expressed concerns about a concept known as the “ratchet effect” when choosing the baseline period from which to calculate target prices. That is, participants do not want to be penalized for achieving lower spending by having lower target prices in subsequent years. The use of fewer years of the most recent baseline episode spending, as well as more frequent rebasing, will generally

decrease target prices more quickly year over year if overall episode spending decreases, as opposed to a longer, fixed baseline. However, we must balance this concern against the likelihood of having inaccurate target prices if we use older baseline episode spending or rebase less frequently.

In TEAM, we finalized a revised version of the BPCI Advanced strategy with a shorter, 3-year baseline that was rebased annually and temporally weighted to place greater emphasis on more recent years. As initially described in final rule establishing TEAM (89 FR 69748), we believe this approach will achieve a balance between providing target prices that sufficiently reflect up-to-date spending trends and mitigating the ratchet effect by allowing prices to adjust more gradually over time. Additionally, as discussed in section X.C.2.f.(3)(b) of this proposed rule, we are proposing regional target prices based on regional average spending making CJR–X an achievement-based model. In this framework, CJR–X participants would not compete against their historical selves but rather strive to outperform their regional peers. Individual improvements will not affect future target prices in a substantive way as the future benchmark is being calculated based on the performance of several hospitals. We believe a 3-year baseline period constructed using all hospital's spending would help produce a fair pricing approach that balances accuracy, simplicity, and mitigates CJR–X participants being penalized for successful past performance.

For CJR–X, we propose to adjust baseline episode spending to trend all episode spending to the most recent year of the baseline period. The adjustment would reflect the impact of inflation and any changes in episode spending due to evolving patterns of care, Medicare payment policies, payment system updates, and other factors during the baseline period. At § 512.605(e) propose to define a “baseline year” as any of the 3 fiscal years during a given baseline period. For example, baseline year 1 for PY 1 will be FY 2024 (October 1, 2023–September 30, 2024), baseline year 2 will be FY 2025 (October 1, 2024–September 30, 2025), and baseline year 3 will be FY 2026 (October 1, 2025–September 30, 2026). We propose to calculate the adjustment factors for baseline years 1 and 2 by dividing average episode spending for baseline year 3 episodes by average episode spending for episodes from baseline years 1 and 2, respectively. We would then apply the applicable adjustment factors to the episode spending of each

episode in baseline years 1 and 2. This adjustment would bring all baseline episode spending forward to the most recent baseline year, so that baseline year 1 and 2 spending would be expressed in baseline year 3 dollars. This method would be consistent with how we calculated the baseline trend factor for CJR in the performance years that used the 3-year baseline period, as described in the 2015 CJR final rule (80 FR 73342). We propose to calculate these baseline trend factor adjustments at the MS–DRG/HCPSC episode type and region level.

In recognition of the fact that baseline episode spending from more recent years are likely to be a better predictor of performance year spending, we propose to weight recent baseline episode spending more heavily than episode spending from earlier baseline years. Specifically, we propose to weight episode spending from baseline year 1 at 17 percent, baseline year 2 at 33 percent, and baseline year 3 at 50 percent. This method of weighting would mean that the most recent episode spending patterns, expected to be the most accurate predictor of performance year spending, would contribute most strongly to the benchmark price at 50 percent. The remaining 50 percent would be divided into thirds, with baseline year 2 contributing approximately  $\frac{2}{3}$ , while baseline year 1, which is likely to be the least accurate predictor of performance year spending, would contribute  $\frac{1}{3}$ .

We seek comment on our proposed definitions at § 512.605 and our proposals at § 512.640(b)(2) and (3) to use 3 years of baseline episode spending, rolled forward for each performance year, with more recent baseline years weighted more heavily, to calculate CJR–X target prices.

#### (b) Regional Target Prices

We are proposing to provide target prices to CJR–X participants for each proposed MS–DRG/HCPSC episode type and region based on 100 percent regional data for all CJR–X participants prior to each PY. This approach would be consistent with PYs 4 through 8 of the CJR Model and aligns with the approach implemented in TEAM (89 FR 69751). While CJR target prices used a blend of two-thirds hospital-specific data and one-third regional data for PYs 1 and 2, and one-third hospital-specific data and two-thirds regional data for PY 3, we stated our reasons in the 2015 CJR final rule for moving towards fully regional target pricing as participants gained more experience in the model (80 FR 73347). Target prices based on hospital-specific data would require a

CJR–X participant to compete against its own previous performance and improve over that performance to receive a reconciliation payment. Conversely, target prices based on regional data would require a CJR–X participant to compete against its peers in that region, such that only a specific level of achievement, as opposed to improvement alone, would result in a reconciliation payment. For historically inefficient CJR–X participants, compared to their peers, hospital-specific target prices would be higher than regional target prices because hospital-specific baseline episode spending would be greater than average baseline episode spending for the region. For CJR–X participants that are historically efficient compared to their peers, hospital-specific target prices would be lower than regional target prices because hospital-specific baseline episode spending would be lower than average baseline episode spending for the region. We noted in the 2015 CJR final rule that if we used 100 percent hospital-specific pricing in CJR, historically efficient hospitals could have fewer opportunities for achieving additional efficiencies under the model and would not be rewarded for maintaining high quality and efficiency, whereas less efficient hospitals would be rewarded for improvement even if they did not reach the same level of high quality and efficiency as the more historically efficient hospitals.

We seek comment on our proposal at § 512.640(b)(1) to provide regional target prices to all CJR–X participants for each PY.

#### (c) Services That Extend Beyond an Episode

As we are proposing a fixed 90-day post-discharge episode length as discussed in section X.C.2.d.(3)(d) of this proposed rule, we recognize that there may be some instances where a service included in the episode begins during the episode but concludes after the end of the episode and for which Medicare makes a single payment under an existing payment system. An example would be a beneficiary in an episode who is admitted to a SNF for 30 days, beginning on day 65 post-discharge from the CJR–X anchor hospitalization or anchor procedure. The first 25 days of the SNF admission would fall within the episode, while the subsequent 5 days would fall outside of the episode. We propose that, to the extent that a Medicare payment for included episode services spans a period of care that extends beyond the episode, these payments would be prorated so that only the portion



attributable to care during the episode is attributed to the episode payment when calculating actual Medicare payment for the episode. For non-IPPS inpatient hospital (for example, CAH) and inpatient PAC (for example, SNF, IRF, LTCH, IPF) services, we propose to prorate payments based on the percentage of actual length of stay (in days) that falls within the episode window. For HHA services that extend beyond the episode, we propose that the payment proration be based on the percentage of days, starting with the first billable service date (“start of care date”) and through and including the last billable service date, that fall within the episode. This proposed policy would ensure that CJR–X participants are not held responsible for the cost of services that did not overlap with the episode period. For IPPS services that extend beyond the episode (for example, readmissions included in the episode definition), we propose to separately prorate the IPPS claim amount from episode target price and actual episode payment calculations, called the normal MS–DRG payment amount for purposes of this proposed rule. The normal MS–DRG payment amount would be prorated based on the geometric mean length of stay, comparable to the calculation under the IPPS PAC transfer policy at § 412.4(f) and as published on an annual basis in Table 5 of the IPPS/LTCH PPS final rules. Consistent with the IPPS PAC transfer policy, the first day for a subset of MS–DRGs (indicated in Table 5 of the IPPS/LTCH PPS final rules) would be doubly weighted to count as 2 days to account for likely higher hospital costs incurred at the beginning of an admission. If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment would be fully allocated to the episode. If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount would be allocated to the episode based on the number of inpatient days that fall within the episode. If the full amount is not allocated to the episode, any remaining amount would be allocated to the 90-day post-episode payment calculation discussed in section X.A.3.(d)(5) of this proposed rule. The proposed approach for prorating the normal MS–DRG payment amount is consistent with the IPPS transfer per diem methodology. This methodology would be consistent with CJR, and is described as applied to CJR in the 2015 CJR final rule (80 FR 73333).

We seek comment on our proposed methodology at § 512.655 for prorating services that extend beyond the episode.

(d) Episodes That Begin in One Performance Year and End in the Subsequent Performance Year

Given that we are proposing episodes with a 90-day post discharge period, we recognize that some episodes will begin during one performance year and end during the following performance year. We propose that all episodes would receive the target price associated with the date of discharge from the anchor hospitalization or the anchor procedure, as applicable, regardless of the episode end date. We note that the assignment of target prices based on the date of discharge from the anchor hospitalization or the anchor procedure is different from the CJR model, where the target price was assigned based on the episode start date rather than the discharge date, but this proposed policy is consistent with BPCI Advanced. This slight modification of using the anchor hospitalization and anchor procedure date of discharge ensures the same approach is applied to target price assignment and reconciliation of episodes. As noted in section X.C.2.f.(5)(a) of this proposed rule, annual reconciliation is based on episodes with a date of discharge from the anchor hospitalization or a date of discharge from the anchor procedure during that PY. So, if an episode starts in one PY and has an anchor hospitalization discharge date that extends past the end of a PY, that episode would factor into the next PY’s reconciliation, which is consistent with TEAM.

We seek comment on our proposal at § 512.640(a)(3) for applying target prices to an episode that begins in one performance year and ends in the subsequent performance year.

(e) High-Cost Outlier Cap for Benchmarking

Given the broad proposed episode definition and 90-day proposed post-discharge period, we want to ensure that hospitals have some protection from the downside risk associated with especially high payment episodes, where the clinical scenarios for these cases each year may differ significantly and unpredictably. As we stated in the 2015 CJR final rule (80 FR 73335), we do not believe that the opportunity for a hospital’s systematic care redesign of particular surgical episode has the significant potential to impact the clinical course of these extremely disparate high payment cases. In the 2015 CJR final rule (80 FR 73335), we

finalized a policy to limit hospital responsibility for high episode payment cases by utilizing a high price payment ceiling at two standard deviations above the mean episode payment amount in calculating the target price and in comparing actual episode payments during the performance year to the target prices. This policy was designed to prevent participant hospitals from being held responsible for catastrophic episode spending amounts that they could not reasonably have been expected to prevent. The policy, and the reasoning behind it, is described in detail at (80 FR 73335). However, as we described in 86 FR 23518, based on data from the first few years of the CJR model, we observed that the original 2 standard deviation methodology was insufficient to identify and cap high episode spending, as more episodes than expected exceeded the spending cap. We describe in detail our reasoning for finalizing a change to the high episode spending cap in the 2021 CJR 3-Year Extension final rule (86 FR 23518). We finalized a change to the calculation of the high episode spending cap to derive the amount by setting the high episode spending cap at the 99th percentile of historical costs for each MS–DRG for each region. The resulting methodology for the CJR Extension was similar to the BPCI Advanced methodology for capping high-cost episode spending at the 99th percentile for each MS–DRG. We propose a similar high-cost outlier policy for CJR–X, which also aligns with TEAM. We propose to cap both baseline episode spending and performance year episode spending at the 99th percentile of spending at the MS–DRG/HCPCS episode type, region and baseline year, referred to as the “high-cost outlier cap” and defined at proposed § 512.605. We propose to determine the 99th percentile of spending at the MS–DRG/HCPCS episode type, region, and baseline year during the applicable time period, and then set spending amounts that exceed the high-cost outlier cap to the amount of the high-cost outlier cap. For instance, if the high-cost outlier cap was set at \$30,000, an episode that had actual episode spending of \$45,000 would have its spending amount, for purposes of the model, reduced by \$15,000 when the cap was applied and therefore, the spending for that episode would be held at \$30,000. We propose to use capped episode spending when calculating benchmark prices in order to ensure that high-cost outlier episodes do not artificially inflate the benchmark. When calculating performance year episode spending at reconciliation, we



propose to use capped episode spending so that a CJR-X participant would not be held responsible for catastrophic episode spending amounts that they could not reasonably have been expected to prevent.

We seek comment on our proposal at § 512.605 to define “high-cost outlier cap” and our proposal at § 512.640(b)(4) for calculating and applying the high-cost outlier cap.

#### (f) Trending Prices

Target prices are derived from a prediction based on previous Medicare spending patterns, but it is not possible to perfectly predict how Medicare spending patterns may change over the course of the performance year. In the original BPCI model, prospective target prices were not provided to participants, so the trend factor was calculated retrospectively based on the observed spending during the performance period. Quarterly reconciliations in BPCI meant that participants could gain a sense of how their target prices tended to change over time and get relatively frequent feedback on their performance in the model. However, BPCI participants expressed concern with the uncertainty of not knowing their target prices in advance.

In the initial CJR methodology and Model Years 1 through 3 of BPCI Advanced, CMS provided fully prospective target prices to participants. Participants appreciated the certainty of prospective target prices, where we predict in advance how spending patterns might shift and hold those target prices firm even if we underpredicted or overpredicted spending. This methodology included applying update factors to account for setting-specific payment system updates, allowing us to estimate how a given set of services performed during the baseline would be priced had those same services been subject to the fee schedules in effect during the performance period.

In CJR, we originally overpredicted performance period spending, not accounting for the overall decline in spending on LEJR episodes nationwide that occurred outside of the model during its first few performance years. In BPCI Advanced, we similarly overpredicted performance period spending for certain episodes because our methodology was unable to account for medical coding changes that occurred between the baseline and performance period, or during the performance period itself. For instance, in FY 2016, changes to medical coding guidance were made for Inpatient

Congestive Heart Failure, such that certain patients who during the baseline would have been coded as the less expensive MS-DRG 292, were instead coded as the more expensive MS-DRG 291. This was done in spite of having the same clinical characteristics. This meant that many beneficiaries who received a target price associated with the more expensive MS-DRG 291, actually had the lower performance period costs previously associated with the less expensive MS-DRG 292. The use of a fully prospective trend factor was unable to capture these changes in both practice patterns and coding guidelines.

Subsequently, we modified both models’ methodologies to include a retrospective trend adjustment. Starting in model year 4, we continued to provide BPCI Advanced participants with a prospective target price using an estimated trend factor, but we adjusted the target price at reconciliation based on the retrospective calculation of the trend factor using performance period data. Initially, this policy included guardrails around the magnitude of the retrospective trend factor adjustment of  $\pm 10$  percent. In response to participant feedback, we lowered the maximum level of the retrospective trend factor adjustment to  $\pm 5$  percent starting in model year 6.

In the CJR Extension, the retrospective trend was known as the market trend factor adjustment. It was fully retrospective and calculated at reconciliation, meaning that the unadjusted target price we posted on the CJR website prior to the performance year did not include a prospective trend factor. In response to participant requests, we provided estimates of the market trend factor on the CJR website based on the most recently available data to help participants estimate their potential target prices. The market trend factor was calculated separately for each MS-DRG/region combination. For the PY 8 reconciliation (corresponding to episodes that ended between January 1, 2024 and December 31, 2024), the highest market trend factor was 1.307 for MS-DRG 469 episodes in the Mountain region, while the lowest market trend factor was 0.998 for MS-DRG 470 episodes in the New England region.

In TEAM, we initially proposed a fully prospective trend factor adjustment based on the percentage difference between average regional MS-DRG/HCPCS episode type expenditures for baseline year 3 (the most recent baseline year) and baseline year 1 (the earliest baseline year) (89 FR 36430). Based on stakeholder feedback,

we ultimately revised this approach to align more closely with the modified BPCI Advanced methodology. As described in the TEAM final rule (89 FR 69755), TEAM participants receive a preliminary target price that incorporates a prospective trend factor adjustment for each MS-DRG/HCPCS episode type and region, which reflects the average annual change in episode spending over the baseline period both regionally and nationally. At reconciliation, a retrospective trend factor adjustment is applied to preliminary target prices based on the average capped performance year episode spending vs. the average capped baseline episode spending. This retrospective adjustment is capped at  $\pm 3$  percent of the prospective trend adjustment in order to maintain predictability for participants. TEAM also further refined their prospective trend approach in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37099) to incorporate a linear regression that includes all years in the baseline period to construct the trend, rather than a trend that only looked at the change from baseline year 1 to baseline year 3. TEAM also finalized the addition of two trend years to capture more years of data in the construction of the trend.

For CJR-X, we are proposing to apply a “prospective trend factor”, defined at proposed § 512.605, as the multiplier incorporated into the preliminary target price to estimate changes in spending patterns between the baseline period and the performance year. We also propose to apply a  $\pm 3$  percent capped “retrospective trend factor”, defined at proposed § 512.605, as the multiplier incorporated into the reconciliation target price to estimate realized changes in spending patterns during the performance year. This methodology would be similar to the approach used in TEAM. The key difference from TEAM is that CJR-X will not include the two trend years in the prospective trend factor, because we want to keep consistent the time frame of data we are sharing with CJR-X participants to the data used to construct target prices. For example, CJR-X would share three years of baseline data with CJR-X participants which would align with the baseline period used to construct the prospective trend, whereas TEAM shares three years of data that encompasses their baseline period but TEAM participants do not receive data associated with the two trend years. We believe using an approach similar with TEAM’s, specifically applying a prospective trend with a  $\pm 3$  percent capped retrospective trend factor, will better

account for significant spending changes that are not accounted for in the baseline while also ensuring that trends in regions where efficiency is improving over time do not overshoot what is feasible, leading to target prices that more accurately reflect spending patterns during the performance period.

Given our proposal to use a prospective trend factor to predict future spending for the purposes of pricing stability, we considered but are not proposing to include update factors that take into account Medicare payment system updates for each FY or CY and could improve pricing accuracy. Specifically, we considered a methodology similar to BPCI Advanced and Performance Years 1–5 of the CJR Model, where preliminary target prices were updated to reflect the most current FY and CY payment system rates using setting-specific update factors for payment system, including the IPPS, OPSS, Physician Fee Schedule (PFS), Home Health Prospective Payment System (HH PPS), Medicare Economic Index (MEI), the IRF PPS, and the SNF PPS. However, updating target prices using setting-specific update factors would result in CJR–X participants receiving more than one target price for an MS–DRG/HCPCS episode type in a performance year which can increase complexity. Further, while including update factors would generally increase target prices, it also decreases pricing stability since the preliminary target price would change due to the application of update factors. However, we are interested in capturing the most accurate episode spending in CJR–X that captures these payment system updates. We have included a proposal in section X.C.2.f.(5)(d). of this proposed rule to account for this by updating the preliminary target price when constructing the reconciliation target price that avoids sharing update factors and having CJR–X participants manage multiple preliminary target prices within a given performance year.

We also considered, but are not proposing, alternative caps on the retrospective adjustment, including  $\pm 5$  percent and  $\pm 10$  percent of the prospective trend adjustment. Ultimately, we believe that a narrower adjustment range would improve stability and predictability for CJR–X participants. A lower cap on retrospective adjustments also mitigates the risk that target prices will be disproportionately impacted by performance year shifts in spending patterns that could not have been foreseen.

We seek comment on our proposal at § 512.640(b)(7) to apply a prospective

trend factor to preliminary target prices and our proposal at § 512.645(f) to apply a retrospective trend factor with a  $\pm 3$  percent cap. We seek comment on our proposals at § 512.605 to define “prospective trend factor” and “retrospective trend factor.”

We are also requesting comment on alternative ways to calculate the trend factor to both increase accuracy of prospective target prices and to mitigate the ratchet effect. We recognize that spending on LEJR episodes has been decreasing over time and may reach a point where further decreases in spending could compromise quality and patient safety. The downward trend in LEJR episode spending we observed in the early years of CJR has stabilized in more recent years, suggesting that there may no longer be as much of an opportunity for participant savings as there was in the early years of CJR. In the case where spending has been decreasing but has since stabilized, trending the episode target price forward based on previous years’ trends could result in target prices that are too low. In such a scenario, a retrospective trend adjustment might actually result in a higher target price than a fully prospective trend. We are seeking comment on ways to construct a trend factor that can result in a reasonable target price regardless of whether spending has been increasing, decreasing, or stabilizing.

For example, in the CY 2023 Physician Fee Schedule final rule, CMS finalized a policy to include a prospectively-determined component, the Accountable Care Prospective Trend (ACPT), in the factor used to update the benchmark to the performance year for ACO agreement periods starting on or after January 1, 2024 (see *87 FR 69881* to *69898*). This would help address the ratchet effect by insulating a portion of the update factor from the impact that ACO savings can have on retrospective national and regional spending trends. This type of trend is referred to as an administrative trend, because it is not directly linked to ongoing observed FFS spending. However, we recognize that there may be some concerns using administrative trends for episode-based payment models, as opposed to population-based payment models like ACOs, because administrative trends may not capture episode-specific trends, which could lead to higher or lower preliminary target prices when compared to actual performance year spending. We request comment on this type of trending approach, or other potential ways to increase the accuracy of prospective target prices and mitigate

the ratchet effect when we update CJR–X target prices.

#### (g) Discount Factor

In addition to the prospective trend factor, at proposed § 512.640(b)(8) we propose to apply a discount factor, defined at proposed § 512.605, to the benchmark price when calculating preliminary target prices. Specifically, we propose to apply a 2 percent discount factor to the benchmark price to serve as Medicare’s portion of reduced expenditures from the episode. This discount would be similar to the 2 percent discount factor applied to LEJR episode target prices in TEAM.

In both the CJR Model and BPCI Advanced, we applied a 3 percent discount to benchmark prices when calculating preliminary target prices for LEJR episodes. However, based on evidence and participant feedback from the final performance years of the CJR Extension, we believe that a 3 percent discount would not be sustainable for an expanded model and could result in more price ratcheting over a longer time horizon.

We also considered but are not proposing lower discount factors including 1.5 percent, 1 percent, or no discount factor. In addition, we considered linking the discount to variability in episode spending during the baseline, such that an episode with minimal variability in baseline spending might have a lower discount percentage, given that lower variability in baseline spending might indicate fewer opportunities for savings. We also considered but are not proposing to incrementally reduce the discount rate over a predetermined timeline and different ways to adjust the Medicare discount over time or based on differential savings opportunities for different episode types.

We seek comment on our proposal at § 512.605 to define “discount factor” and on our proposal at § 512.640(b)(8) to apply a 2 percent discount factor to preliminary episode target prices for CJR–X. We also seek comment on alternative discounts and discount adjustments.

#### (h) Special Considerations for Low Volume Hospitals

In both the CJR Model and BPCI Advanced, we recognized that hospitals that perform a number of episodes below a certain volume threshold would have insufficient volume to receive a target price based on their own baseline data. In the 2015 CJR final rule (*80 FR 73285*), we acknowledged that such hospitals might not find it in their financial interests to make systemic care

redesigns or engage in an active way with the CJR model. At *80 FR 73292*, we acknowledged commenter concerns about low volume providers, including but not limited to, observations that low volume providers could be less proficient in taking care of LEJR patients in an efficient and cost-effective manner, more financially vulnerable with fewer resources to respond to the financial incentives of the model, and disproportionately impacted by high-cost outlier cases. In spite of these potential challenges, we stated that the inclusion of low volume hospitals in the CJR Model was consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure, care redesign experience, market position, and other considerations and circumstances (*80 FR 73292*).

In the CJR Model, we set the low volume threshold as fewer than 20 LEJR episodes across the 3-year baseline years of 2012 through 2014. Low volume hospitals received target prices based on 100 percent regional data, rather than a blended target price that incorporated their participant-specific data, because a target price based on limited data is less likely to be accurate and reliable. These hospitals were also subject to the lower stop-loss limits that we offered to rural hospitals, in recognition of the fact that they might be less prepared to take on downside risk than hospitals with higher episode volume. In the CJR 2017 final rule that reduced the number of mandatory MSAs, low volume hospitals were among the types of hospitals that were required to opt in if they wanted to remain in the model (*82 FR 57072*). In the 2020 final rule, we removed the remaining low volume hospitals from the CJR Extension when we limited the “participant hospital” definition to those hospitals that had been mandatory participants throughout the model (*86 FR 23497*).

In BPCI Advanced, our low volume threshold policy was to not provide a target price for a given clinical episode category if performed at a hospital that did not meet the 41 clinical episode minimum volume threshold during the 4-year baseline period. This meant that no BPCI Advanced episodes would be triggered for that particular clinical episode category during the applicable performance period at that hospital. However, participants could continue to trigger other clinical episode categories for which they had enrolled and for which there was sufficient baseline volume. Additionally, clinical episodes that occurred at the hospital during the performance period, though not

triggering a BPCI Advanced episode, would count toward the low volume threshold when that year became part of the baseline. Therefore, as the baseline shifted forward each year, bringing a more recent year into the baseline and dropping the oldest year, a hospital could potentially meet the volume threshold and receive a target price for the clinical episode category for a subsequent performance period.

In TEAM, if a TEAM participant does not meet the minimum baseline threshold of at least 31 episodes in a given episode category during the baseline period, the hospital’s episodes are included in reconciliation calculations, but the hospital will not be held financially accountable for spending that exceeds the target price for that episode category in that performance year. This effectively waives downside financial risk for the hospital for any episode categories in which it did not meet the low-volume threshold, providing protection against undue financial exposure while still allowing the hospital to participate in the model and benefit from savings, if applicable. We believe this policy is appropriate for TEAM given the increased number of episode categories mandatorily tested compared to the original CJR model and its time-limited test compared to longer-term CMS initiatives.

For CJR–X, we are proposing a low volume policy that aligns with the approach we tested in BPCI Advanced because low volume hospitals were voluntary and ultimately removed from participation at the time of CJR Extension. We do not believe removing or excluding low volume hospitals is a good long-term policy for CJR–X since we recognize episode volumes can change over time. Also, there also may be instances when a hospital is just starting out and may have low volumes but then ramp up operations and see a substantial number of beneficiaries for LEJR procedures. Thus, we believe a better policy for CJR–X would be to have a low volume policy that is responsive to episode volume changes year over year and acknowledges hospitals with low volume may not have the ability to spread risk when there is an insufficient number of procedures being performed. We propose at § 512.605 to define “low-volume hospital” as a hospital with fewer than 31 LEJR episodes performed during the applicable baseline period. We propose at § 512.640(a)(4) that low-volume hospitals would be excluded from reconciliation for the performance year. As in BPCI Advanced, hospitals that do not meet the minimum volume

threshold for a given performance year would not trigger CJR–X episodes or receive a target price. Any LEJR episodes performed at these hospitals during the performance year would be excluded from regional benchmark calculations, although they would count toward the low volume threshold when that year becomes part of the baseline. Therefore, as the baseline shifts forward each year, bringing a more recent year into the baseline and dropping the oldest year, a hospital could potentially meet the volume threshold and trigger CJR–X episodes for a subsequent performance period.

We considered implementing minimum episode volume thresholds during the performance year. Specifically, we considered excluding CJR–X participants from reconciliation if they initiate fewer than 10 or 15 LEJR episodes during that performance year. However, we are concerned that including minimum episode volume thresholds during the performance year may introduce program integrity issues where CJR–X participants steer CJR–X beneficiaries to other providers to be below the threshold and not be accountable for episodes in CJR–X.

We seek comment on our proposal at § 512.605 to define “low-volume hospital” and our proposal at § 512.640(a)(4) for setting and applying the low volume threshold at reconciliation.

#### (i) Preliminary Target Prices

We propose to define “preliminary target price” as the target price provided to the CJR–X participant prior to the start of the performance year, which is subject to adjustment at reconciliation. We propose at § 512.640(b)(9) that CMS would provide preliminary target prices to CJR–X participants, in a form and manner specified by CMS, prior to the start of each performance year. For instance, since the earliest episodes for a given performance year would end on January 1, and most of these episodes would have been initiated by an anchor hospitalization or anchor procedure that occurred near the end of November or the beginning of December of the previous calendar year, we propose to provide preliminary target prices to the CJR–X participant by the end of November prior to each performance year. We propose that preliminary target prices would be based on regional episode spending during the baseline period. CJR–X participants would receive the preliminary target prices for each MS–DRG/HCPSC episode type that corresponded to their region. We propose that these preliminary target prices would incorporate a prospective

trend factor (as described in section X.C.2.f.(3)(f). of this proposed rule) and a discount factor (as described in section X.C.2.f.(3)(g). of this proposed rule), as well as a prospective normalization factor (as described in section X.C.2.f.(4). of this proposed rule).

We seek comment on our proposal at § 512.640(b)(9) to provide preliminary target prices to CJR–X participants prior to the start of each performance year.

#### (4) Risk Adjustment and Normalization

In the original CJR Model methodology, we first proposed that risk adjustment be limited to providing separate target prices for episodes initiated by MS–DRG 469 versus MS–DRG 470, because MS–DRGs under the IPPS are designed to account for some of the clinical and resource variations that exist and that impact hospitals' costs of providing care (*80 FR 73338*). In response to comments requesting further risk adjustment, in the 2015 CJR final rule we finalized a policy to risk adjust target prices based on the presence of a hip fracture diagnosis code in order to capture a significant amount of patient-driven episode expenditure variation (*80 FR 73339*). As a result, we provided four separate target prices to participant hospitals based on MS–DRG 469 versus MS–DRG 470, and presence versus absence of a primary hip fracture. The impact of hip fractures on inpatient costs associated with a hip replacement was subsequently acknowledged by CMS' decision to create two new MS–DRGs (521 and 522) for hip replacements in the presence of a primary hip fracture (*85 FR 58432*). We incorporated these new MS–DRGs into the CJR Model episode definition as of October 1, 2020 via the November 2020 Interim Final Rule with Comment (IFC) (*85 FR 71170*).

In the 2021 CJR 3-Year Extension final rule, we acknowledged the need for further risk adjustment to account for beneficiary-level factors that tend to impact spending in a way that is beyond the control of the provider. We introduced age bracket (less than 65 years, 65 to 74 years, 75 to 84 years, and 85 years or more), CJR HCC count (zero, one, two, three, and four or more), and dual eligibility (receiving both full Medicare and Medicaid benefits) as beneficiary-level risk adjustment factors that would be applied to each episode at reconciliation. The definition of these risk adjustment variables, and our reasoning for incorporating them into the risk adjustment methodology, is described in detail at *86 FR 23523*.

The coefficients for the risk adjustment variables in the CJR Extension were calculated prospectively, prior to the beginning of each performance year, using a linear regression model. As we stated at *86 FR 23524*, this regression model approach would allow us to estimate the impact of each risk adjustment variable on the episode cost of an average beneficiary, based on typical spending patterns for a nationwide sample of beneficiaries with a given number of CMS–HCC conditions, within a given age bracket, and with dual eligibility or non-dual eligibility status. We used an exponential model to account for the fact that LEJR episode costs are not normally distributed. A detailed description of the regression model begins at *86 FR 23524*.

At reconciliation, after applying the high-cost episode cap to remove outliers, the risk adjustment coefficients for the three risk adjustment variables were applied to the episode-level target price based on the applicable episode region and MS–DRG. However, since age, CJR HCC count, and dual eligibility status are inherently included in the regional target price, since regions with beneficiaries who are older, more medically complex, and socioeconomically disadvantaged tend to have higher average episode costs, we applied a normalization factor to remove the overall impact of adjusting for age, CJR HCC count, and dual eligibility on the national average target price, as described at *86 FR 23527*.

By contrast, BPCI Advanced used a more complex risk adjustment model that included many more risk adjustment coefficients, including both patient and provider characteristics. Categories of patient characteristics included (but were not limited to): HCCs (individual flags, interactions, and counts), recent resource use, and demographics. Provider characteristics, which were used to group hospitals into peer groups, included bed size, rural vs. urban, safety net vs. non-safety net, and whether or not the participant was a major teaching hospital. The first stage of the BPCI Advanced risk adjustment methodology used a compound log-normal model in order to account for the substantial right skew of the distribution of episode costs. This means that it combined two log-normal distributions in order to capture costs associated with both low-cost episodes (which were the majority of episodes) and very high-cost episodes (which were fewer in number but exerted a strong influence on spending averages). However, participants found this risk adjustment model difficult to interpret,

particularly since it was not widely used in other research or healthcare models.

For TEAM, in an effort to simplify the risk adjustment methodology and allow participants to more easily calculate an episode-level estimated target price, we based our methodology on the CJR Extension methodology, with a few key differences. Rather than calculating one national set of risk adjusters across all MS–DRGs for a given episode category, we calculate risk adjustment coefficients at the MS–DRG/HCC episode type level. We considered calculating risk adjustment at the MS–DRG/HCC episode type/region level, but we believed that, when further subdivided into regions, the low volume of episodes for certain MS–DRG/HCC episode types would be insufficient to create accurate and reliable risk adjustment multipliers.

In the TEAM proposed rule, we initially proposed to use three beneficiary-level risk adjustment variables that were similar to the CJR Extension methodology, with two key differences. First, instead of using the annual HCC file to calculate the HCC count variable, we proposed to conduct a 90-day lookback of FFS Medicare claims for each beneficiary, beginning with the day prior to the anchor hospitalization or anchor procedure, and count the number of HCC flags assigned. We subsequently revised this to a 180-day lookback in the final rule (*90 FR 37105*). Second, instead of a dual-eligibility risk adjustment variable, we proposed a more comprehensive approach which accounted for dual eligibility status, as well as Low Income Part D Subsidy qualification and area-level socioeconomic deprivation. As discussed in the TEAM final rule (*90 FR 37103*), this beneficiary economic risk adjustment functions as a binary (yes=1, no=0) variable, with a value of 1 being assigned to episodes where the beneficiary meets at least one of the following three criteria as of the first day of the episode: (1) resides in an area that exceeds the 80th percentile threshold for National Community Deprivation Index; (2) eligible for Medicare Part D Low Income Subsidy; and (3) eligible for full Medicaid benefits.

In addition to the three initially proposed risk adjustment variables, several additional beneficiary and participant-level risk adjustments were added to the TEAM target price methodology in response to public comments. This includes hospital-level adjustments for bed size (250 beds or fewer, 251–500 beds, 501–850 beds, or 851+ beds) and safety net status, as

defined in 42 CFR 512.505.

Additionally, TEAM applies several episode category-specific beneficiary risk adjustment factors to target prices that were not used in the CJR Extension. These episode category-specific risk adjustment factors reflected the presence or absence of certain conditions or services during the 180-day lookback period. For the LEJR episode category, this includes binary risk adjustments (yes=1, no=0) for prior post-acute care use, disability as the original reason for Medicare enrollment, LEJR procedure, and 21 HCC flags, as detailed in 42 CFR 512.545(a)(6)(ii), including, but not limited to, morbid obesity [HCC 48] and diabetes with severe acute [HCC 36] or chronic [HCC 37] complications. The decision to risk adjust based on individual HCCs, in addition to the aggregate HCC count adjustment, was intended to reflect the differential effects that individual chronic conditions like diabetes or chronic kidney disease can have on total episode spending, allowing us to provide more accurate and nuanced target prices.

Another key difference between the TEAM and CJR Extension risk adjustment methodologies is that, in TEAM, we provide a prospective normalization factor with preliminary target prices. This prospective normalization factor is subject to a limited adjustment at reconciliation based on the observed case mix, up to +/- 5 percent. This allows participants to better estimate their target prices, as it incorporates the normalization factor prospectively, rather than only introducing the normalization factor at reconciliation. We believe that this approach strikes a balance between predictability and protecting TEAM participants and CMS from significant shifts in patient case mix between the final baseline year and the performance year.

For CJR-X, we are proposing at § 512.645 to use the same risk adjustment methodology and variables, as defined at proposed § 512.605, that are used in TEAM. Specifically, we propose the following:

- To risk adjust target prices at the hospital level using a hospital bed size risk adjustment factor and a safety net risk adjustment factor.
- To risk adjust target prices at the beneficiary level using a 180-day lookback period to construct a “CJR-X HCC count risk adjustment factor”, an “age bracket risk adjustment factor”, a “beneficiary economic risk adjustment factor”, and based on certain conditions or HCCs in the 180-day lookback period including—

++ Ankle procedure or reattachment, partial hip procedure, partial knee arthroplasty, total hip arthroplasty or hip resurfacing procedure, and total knee arthroplasty;

++ Disability as the original reason for Medicare enrollment;

++ Prior post-acute care use;

++ HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic;

++ HCC 36: Diabetes with Severe Acute Complications;

++ HCC 37: Diabetes with Chronic Complications;

++ HCC 48: Morbid Obesity;

++ HCC 125: Dementia, Severe;

++ HCC 126: Dementia, Moderate;

++ HCC 127: Dementia, Mild or Unspecified;

++ HCC 151: Schizophrenia;

++ HCC 155: Major Depression, Moderate or Severe, without Psychosis;

++ HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia;

++ HCC 224: Acute on Chronic Heart Failure;

++ HCC 225: Acute Heart Failure (Excludes Acute on Chronic);

++ HCC 226: Heart Failure, Except End-Stage and Acute;

++ HCC 238: Specified Heart Arrhythmias;

++ HCC 253: Hemiplegia/Hemiparesis[

++ HCC 267: Deep Vein Thrombosis and Pulmonary Embolism;

++ HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders;

++ HCC 326: Chronic Kidney Disease, Stage 5;

++ HCC 327: Chronic Kidney Disease, Severe (Stage 4);

++ HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle;

++ HCC402: Hip Fracture/Dislocation.

- Include a “prospective normalization factor” that would be subject to a limited adjustment at reconciliation based on the observed case mix, up to +/- 5 percent to construct the “final normalization factor”. This is inclusive of TEAM’s proposal to include the full baseline period in the construction of the prospective normalization factor, as discussed in section X.A.2.c.(3) of this proposed rule.

As described in section X.C.2.f.(1)(c) of this proposed rule, TEAM was designed to blend and improve upon policies from both BPCI Advanced and the CJR Model based on the cumulative evidence from both model tests. For CJR-X, we propose adopting the TEAM

risk adjustment methodology as it represents a balanced evolution from prior models. The original CJR approach, while straightforward, was deficient in accounting for key patient and provider complexities. In contrast, the BPCI Advanced model offered precision but proved too complex for participants to interpret. The TEAM methodology synthesizes the best of both, integrating more precise adjustments for specific conditions and socioeconomic factors—thus improving upon CJR’s simplicity—without sacrificing the transparency that was lost in BPCI Advanced. This balanced approach makes TEAM the superior foundation for CJR-X, ensuring target prices are both equitable and actionable.

We considered, but are not proposing, a more nuanced approach to the safety net hospital risk adjustment that segmented hospitals into 3 or more groups based on the share of FFS inpatient episodes provided to dual-eligible beneficiaries. We recognize that a binary risk adjustment for safety net hospitals may not accurately reflect the financial challenges for participants with a high percentage of dual-eligible episodes that do not meet the threshold for being classified as a safety net hospital, as defined in proposed § 512.605. For example, the financial challenges faced by hospitals that fall just below the threshold are likely similar to those for hospitals that fall just above it. Furthermore, we recognize that for participants on the margin, their status as a safety net hospital may change from year to year due to random variance and that this may not reflect the more persistent nature of the underlying challenges that the risk adjustment is attempting to address. However, we are concerned that the further segmentation of hospitals into smaller groups may result in sample size and accuracy problems. We propose that a safety net hospital in CJR-X is a hospital in the top 25th percentile in their region for percentage of FFS LEJR inpatient episodes provided to dually eligible beneficiaries during the applicable baseline period. We seek comment on the proposal § 512.605 to use a binary safety net hospital risk adjustment.

To summarize, for CJR-X we propose a risk adjustment methodology based on the TEAM methodology. As in both TEAM and the CJR Extension, we propose to use baseline data to calculate risk adjustment multipliers and hold them constant at reconciliation. We propose that participants would be provided with these risk adjustment multipliers prior to the start of the performance year and would be able to

use them to estimate their episode-level target prices. We propose that, as in TEAM, these risk adjustment multipliers would be calculated at the MS-DRG level, resulting in a separate set of risk adjustment multipliers for each MS-DRG episode type. We also propose to incorporate a prospective normalization factor into preliminary target prices, which would be subject to a limited adjustment at reconciliation.

We seek comment on our proposals at § 512.645(a-d) for risk adjusting episodes and at § 512.605 for the definitions of “age bracket risk adjustment factor”, “beneficiary economic risk adjustment factor”, “CJR-X HCC count risk adjustment factor”, “final normalization factor”, “prospective normalization factor”, and “safety net hospital”.

#### (5) Proposed Process for Reconciliation

In the CJR Model, we performed an annual reconciliation calculation to compare CJR Model PY spending for a CJR participant to a reconciliation target price in order to determine if CMS owed the CJR participant a reconciliation payment, or if the CJR participant owed CMS a repayment. This section outlines our proposals for conducting an annual reconciliation process in CJR-X. As was the case in the CJR Model, we propose to incorporate the participant's quality performance into the reconciliation calculation by adjusting the reconciliation target price for quality based on the CJR-X participant's CQS, which would be constructed from their performance on the proposed quality measures discussed in section X.C.2.e. of this proposed rule. The proposed quality adjustment is discussed in more detail in section X.C.2.f.(5)(f) of this proposed rule. We propose to update the trend factor as discussed in section X.C.2.f.(3)(f) of this proposed rule, and apply episode-level risk adjustment and update the normalization factor as discussed in X.C.2.f.(4) of this proposed rule. We propose to calculate the difference between the participant's aggregated reconciliation target price across all episodes and their episode spending to create the raw NPRA. We propose to apply stop-loss/stop-gain limits to the raw NPRA to determine the CJR-X participant's NPRA. Finally, we propose to subtract the post-episode spending amount from the NPRA, when applicable, to determine the reconciliation payment or repayment amount.

We refer readers to section X.C.2.d.(3) of this proposed rule for our definition of related services for our episodes, to section X.C.2.a of this proposed rule for our definition of performance years, and

to section X.C.2.f.(3) of this proposed rule for our approach to establish preliminary target prices.

#### (a) Annual Reconciliation

As we did in the CJR Model, we propose to conduct an annual reconciliation calculation that would compare performance year spending on episodes with a date of discharge from the anchor hospitalization or a date of discharge from the anchor procedure during that PY with reconciliation target prices for those episodes to calculate a reconciliation amount for each CJR-X participant. We would reconcile, on an annual basis, all episodes attributed to a CJR-X participant that end in a given fiscal year during the performance period. As we stated in the 2015 CJR final rule that finalized the CJR Model (80 FR 73385) and reiterated in the FY 2025 IPPS/LTCH PPS final rule that finalized TEAM (89 FR 69773), we believe that one annual reconciliation accommodates the need for regular performance feedback while minimizing the administrative burden of more frequent reconciliations.

We seek comment on this proposal at § 512.650 to conduct one reconciliation for each performance year.

#### (b) Timing

We propose to conduct the annual reconciliation of each CJR-X participant's actual episode payments against the target price(s) roughly 6 months after the end of the performance year, consistent with the 6 months of claims runout we allowed for the reconciliation in the CJR Extension for CJR Model PYs 6 through 8. As we stated in the 2021 CJR 3-Year Extension final rule that finalized the CJR Extension (85 FR 23519) and reiterated in the FY 2025 IPPS final rule that finalized TEAM (89 FR 69773), we believe that 6 months is sufficient time for claims runout given that an internal review of Medicare claims data found that 98.71 percent of IP claims had been received, and 89.96 percent were considered final, by 6 months after the date of service.<sup>482</sup> For HOPD claims, those rates were 98.10 percent and 95.78 percent, respectively. Similar rates were found for all other types of claims, including Carrier, SNF, HH, and DME, indicating that we would have a nearly complete picture of performance year spending by 6 months after the end of the performance year. Since we are proposing that CJR-X performance years will align with the fiscal year (October

to September) rather than the calendar year, we propose to capture claims submitted by April 1st following the end of the performance year and carry out the NPRA calculation as described previously to make a reconciliation payment or hold CJR-X participants responsible for repayment.

We seek comment on our proposal at § 512.560(b) to perform reconciliation 6 months after the end of the performance year.

#### (c) Participants That Experience a Reorganization Event

In the CJR Model, we recognized that there could be CJR participants that experience a reorganization event during a given performance year. We are proposing to align CJR-X policies for reorganization events with those of the CJR Model. At proposed § 512.605, we propose to define a “reorganization event” as a merger, consolidation, spin-off or other restructuring that results in a new hospital entity under a given CCN. As a result of such an event, the CJR-X participant may begin billing under a different CCN, or an additional entity could be incorporated into the CJR-X participant's existing CCN, resulting in a new hospital entity. For instance, CJR-X participant A may merge with, or be purchased by, CJR-X participant B and begin billing under CJR-X participant B's CCN. In this case, we propose to perform separate reconciliation calculations for CJR-X participant A and CJR-X participant B for those episodes where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the merger or purchase. We propose to reconcile episodes where the anchor hospitalization admission or the anchor procedure occurred on or after the effective date of the merger or purchase under the new or surviving CCN that applies to the blended entity. We are proposing this policy in recognition that the blended entity may have different spending patterns, or a different overall patient case mix, than the two separate entities prior to the merger. In a different instance, if a CJR-X participant merges into or is purchased by a hospital that is excluded from CJR-X participation as specified in proposed § 512.610(b) and begins billing under the CCN of the non-CJR-X participant, we propose to reconcile episodes for the CJR-X participant where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the merger or purchase. This policy would allow for the CJR-X participant to earn a reconciliation payment or owe a repayment for the episodes that

<sup>482</sup> Chronic Conditions Data Warehouse: Medicare Claims Maturity White Paper <https://www2.cdwdata.org/documents/10280/19002256/medicare-claims-maturity.pdf>.

occurred during the portion of the performance year that they were in the model. However, once the CJR–X participant begins to bill under the non-CJR–X participant’s CCN, the blended entity would not be considered a CJR–X participant and we would not reconcile episodes where the anchor hospitalization admission or the anchor procedure occurred on or after the effective date of the merger or purchase under the new or surviving CCN that applies to the blended entity.

We seek comment on our proposal at § 512.650(b)(2) for conducting reconciliations for CJR–X participants that experience a reorganization event during a given performance year.

#### (d) Updating Preliminary Target Prices To Create Reconciliation Target Prices

As discussed in sections X.C.2.f.(3)(f) and X.C.2.f.(4) of this proposed rule, we are proposing to apply beneficiary-level risk adjustment and a limited adjustment to the prospective trend factor and normalization factor, as applicable, to increase the accuracy of our reconciliation calculations. At the time of reconciliation, we would apply these adjustments, if applicable, to the preliminary target prices we calculated and communicated to CJR–X participants prior to the applicable performance year, as described in Section X.C.2.f.(5)(d) of this proposed rule. Additionally, preliminary target prices would be adjusted for geographic wage factor updates, similar to the CJR Model, to convert target prices, which were previously expressed in standardized dollars, into “real” or unstandardized amounts. Application of these adjustments to the preliminary target price, in addition to the Composite Quality Score adjustment described in section X.C.2.f.(5)(e) of this proposed rule, will result in the reconciliation target price. We note that in some cases, the final target price applied to an episode in a given performance year at reconciliation will not change. In addition, in some cases the reconciliation target price will increase from the preliminary target price provided prior to the performance year, potentially benefiting CJR–X participants. For instance, if the prospective trend was 0.98 and the prospective normalization factor were calculated as 0.85, but the realized spending trends and beneficiary case mix during the performance year differed from the values constructed for preliminary target prices, such that the capped retrospective trend adjustment factor was 1.10 and the capped final normalization factor were calculated as 0.87, the reconciliation target price

would incorporate these updated factors and therefore be higher than the preliminary target price.

Furthermore, we recognize that due to the availability of data and the timing of when preliminary target prices would be shared with CJR–X participants, the most up-to-date payment data from CMS payment rules, including the Calendar Year OPPS/ASC rule and the Fiscal Year IPPS/LTCH PPS rule would not be captured in the prices. Typically, CMS proposes and finalizes coding or rate changes, as applicable, through established annual payment rules. While we recognize the retrospective trend factor adjustment will take into account realized spending trends during the performance year, given the proposed 3 percent cap, we are concerned the retrospective trend factor adjustment may not capture payment rate changes or other changes, such as ambulatory payment classification (APC) or MS–DRG changes that arise from these payment rules. Therefore, we propose at § 512.645(g) during reconciliation target price construction to update the preliminary target price to account for updated payment rule changes to reflect episode spending during the performance year. We recognize that accounting for payment rule changes during reconciliation target price construction rather than sharing updated preliminary target prices during the performance year may result in CJR–X participants not having the most updated information during the performance year. We note this methodology differs from TEAM’s proposal in section X.A.2.c.(2) of this proposed rule. We believe this approach is appropriate for CJR–X given the single episode category tested in CJR–X and anticipate fewer coding changes affecting the LEJR episode. We considered but are not proposing to update and deliver preliminary target prices to CJR–X participants for each calendar and fiscal year final rule. We believe managing three different preliminary target prices in a given performance year will increase participant burden and pricing methodology complexity. Lastly, we also considered but are not proposing removing the 3 percent capping of the retrospective trend factor adjustment. Applying a full retrospective trend factor to reconciliation target prices, rather than capping at 3 percent would account for actual performance year spending and would incorporate payment rule changes not captured in preliminary target prices. However, we recognize that removing the 3 percent cap may introduce target price

instability making it more difficult for CJR–X participants to predict reconciliation target prices and assess spending performance in the model.

We seek comment on our proposal at § 512.645(g) to account for payment system changes during the construction of reconciliation target prices.

#### (e) Applying Composite Quality Score to Reconciliation Target Prices

##### (i) Overview

Similar to the CJR Model, we proposed in section X.C.2.f.(3)(g) of this proposed rule to include a discount factor for all CJR–X participants that would be incorporated into preliminary target prices. While the CJR Model included a 3.0 percent discount factor (80 FR 73353), we are proposing a 2.0 percent discount factor for CJR–X that takes into consideration the opportunity for CJR–X participants to find savings and acknowledges the reductions in LEJR spending since the CJR Model was implemented. CJR–X participants that provide high-quality episode care would have the opportunity to reduce the effective discount factor used to calculate their reconciliation target price. As in the CJR Model, we are proposing to adjust the discount factor based on the CJR–X participant’s composite quality score by categorizing them into one of four categories, specifically “Excellent,” “Good,” “Acceptable,” and “Below Acceptable,” for each performance year. Based on where the CJR–X participant is categorized, then they may receive a reduction to their discount factor, no reduction to their discount factor, or no reduction and ineligibility to receive a reconciliation payment.

##### (ii) Adjusting the Discount Factor

We propose to incorporate the composite quality score, as described in section X.C.2.e.(6) in this proposed rule, in the CJR–X pricing methodology by (1) requiring a minimum composite quality score for reconciliation payment eligibility if the CJR–X participant’s actual episode payments are less than the reconciliation target price and (2) determining the effective discount factor included in the reconciliation target price experienced by the CJR–X participant in the reconciliation process.

Under this methodology, we propose CJR–X participants must achieve a minimum composite quality score of  $\geq 6.1$  to be eligible for a reconciliation payment if actual episode spending were less than the reconciliation target price based on the 2.0 percent maximum discount factor. We propose at § 512.645(h)(4) that CJR–X



participants with “below acceptable” quality performance reflected in a composite quality score less than or equal to 6.0 would not be eligible for discount factor reduction nor would they be eligible for a reconciliation payment if actual episode spending were less than the reconciliation target price. A level of quality performance that is below acceptable would not affect CJR–X participants’ repayment responsibility if actual episode spending exceeded the reconciliation target price. We believe that excessive reductions in utilization that lead to low actual episode spending and that could result from the financial incentives of the model would be limited by a requirement that this minimum level of quality be achieved for reconciliation payments to be made. This policy would encourage CJR–X participants to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these CJR–X participants would be ineligible to receive a reconciliation payment if actual episode spending were less than the reconciliation target price.

We propose at § 512.645(h)(3) that CJR–X participants with an “acceptable” composite quality score of greater than or equal to 6.1 and less than or equal to 12.0 would be eligible for a reconciliation payment if actual episode spending were less than the

reconciliation target price but would not be eligible for a discount factor reduction. Therefore, acceptable performance would be based on a 2.0 percent discount factor because their quality performance was at the acceptable level established for the model. These CJR–X participants would be eligible to receive a reconciliation payment if actual episode spending were less than the reconciliation target price.

We propose at § 512.645(h)(2) that CJR–X participants with a “good” composite quality score of greater than or equal to 12.1 and less than or equal to 17.0 would be eligible for a reconciliation payment if actual episode spending were less than the reconciliation target price and would be eligible for a 1.0 percent discount factor that reflects their good quality performance. Thus, participants achieving this level of quality would either have less repayment responsibility (that is, the reduced discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise if the 2.0 discount factor were maintained.

Finally, we propose at § 512.645(h)(1) CJR–X participants with an “excellent” composite score quality score of greater

than or equal to 17.1 would be eligible to receive a reconciliation payment if actual episode spending was less than the reconciliation target price and would be eligible for a 0.0 percent discount factor that reflects their excellent performance. Thus, participants achieving this level of quality would either have less repayment responsibility (that is, the reduced discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise if the 2.0 discount factor were maintained.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section X.C.2.f.(5)(g) of this proposed rule would not change. We believe this approach to quality incentive payments based on the composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under CJR–X to the potential benefit of CJR–X participants and their collaborators as well as CMS and would be consistent with the original CJR model methodology linking quality and payment.

The proposed CJR–X composite quality score ranges are displayed in Table X.C.-05.

**TABLE X.C.-05: RELATIONSHIP OF COMPOSITE QUALITY SCORE ON RECONCILIATION PAYMENT ELIGIBILITY AND DISCOUNT FACTOR**

| Composite quality score (CQS) | Composite Quality Score Category | Eligible for Reconciliation Payment | Discount Factor |
|-------------------------------|----------------------------------|-------------------------------------|-----------------|
| CQS ≤6.0                      | Below acceptable                 | No                                  | 2.0             |
| CQS ≥6.1 and <12.0            | Acceptable                       | Yes                                 | 2.0             |
| CQS ≥12.1 and ≤17.0           | Good                             | Yes                                 | 1.0             |
| CQS ≥17.1                     | Excellent                        | Yes                                 | 0.0             |

We seek comment on our proposal at § 512.650(g) to link quality to payment by adjusting the discount factor for reconciliation target prices.

**(f) Calculating the Raw Net Payment Reconciliation Amount (NPRM)**

Consistent with the original CJR model, after the completion of a performance year, we propose to retrospectively calculate a CJR–X participant’s actual episode performance based on the episode definition. We note that episode spending would be subject to proration for services that extend beyond the

episode (as described in section X.C.2.f.(3)(c) of this proposed rule). We propose to cap performance year spending at the high-cost outlier cap as described in section X.C.2.f.(3)(e) of this proposed rule. We propose to apply the high-cost outlier cap to episodes in the performance year similarly to how we propose to apply it to baseline episodes, using the 99th percentile for each MS–DRG/HCPCS episode type and region as the maximum. Any performance year episode spending amount above the high-cost outlier cap would be set to the amount of the high-cost outlier cap. Similar to the CJR

Model, we would apply geographic wage factors to total capped episode spending to convert the amount from standardized dollars into “real” or unstandardized amounts. We then propose to compare each CJR–X participant’s performance year spending to its reconciliation target prices, calculated as discussed in X.C.2.f.(5)(d) of this proposed rule. We note that, as discussed in section X.C.2.f.(3)(i) of this proposed rule, a CJR–X participant would have multiple target prices for episodes ending in a given performance year, based on the MS–DRG/HCPCS episode type and the performance year



when the episode was initiated. We propose to determine the applicable reconciliation target price for each episode using the aforementioned criteria, and then determine the raw NPRA by calculating the difference between each CJR-X participant's aggregated performance year spending and its aggregated reconciliation target price for all episodes in the performance year.

We seek comment on our proposal at § 512.650(c)(1) through (c)(5) for calculating the raw NPRA.

#### (g) Limitations on NPRA

As we did in the CJR Model, we propose to include both stop-loss and stop-gain limits on the total amount that a CJR-X participant could owe to CMS as a repayment or receive from CMS as a reconciliation payment. As we stated in the 2015 CJR final rule (80 FR 73398), we acknowledge that CJR-X participants vary with respect to their readiness to function under an episode payment model with regard to their organizational and systems capacity and structure, as well as their beneficiary population served. Conversely, we also note that CJR-X participants may be incentivized to excessively reduce or shift utilization outside of the CJR-X episode, even with the proposed quality requirements discussed in section X.C.2.e. of this proposed rule. In order to ensure that CJR-X participants would neither be subject to an unmanageable level of risk nor be incentivized to stint on care to achieve savings, we propose limiting a CJR-X participant's NPRA through the application of symmetrical stop-loss and stop-gain limits, calculated as a percentage of the hospital's aggregate reconciliation target price. We note that the stop-loss limit would not apply to any post-episode spending amount as discussed in section X.C.2.f.(5)(h). of this proposed rule.

Consistent with the CJR Model, we propose a stop-loss and stop-gain limit of 20 percent for most CJR-X participants. We believe maintaining consistency with the CJR Model's 20 percent stop-loss and stop-gain limits for most CJR-X participants provides an appropriate balance of financial risk and reward to promote spending reductions with reasonable risk thresholds. However, we also acknowledge that certain groups of CJR-X participants may have lower risk tolerance and less infrastructure and support to achieve efficiencies for high-cost episodes, as we stated in the 2015 CJR final rule (80 FR 73403). Therefore, we propose to provide additional safeguards to certain categories of CJR-X participants, largely

consistent with the CJR Model. We propose to apply a 5 percent stop-loss for CJR-X participants that are rural hospitals as defined at proposed § 512.605, Medicare-dependent, small rural hospitals (MDH), and sole community hospitals (SCH). We also propose to apply a 5 percent stop-loss for CJR-X participants that meet the proposed definition of safety net hospitals, as defined at proposed § 512.605. Although we did not apply this additional stop-loss protection to safety net hospitals in the CJR Model, evaluation results indicated that this category of hospital was disproportionately likely to owe repayments to Medicare, as we discuss in section X.C.2.f.(4). of this proposed rule.

We seek comment on our proposal at § 512.650(c)(6)(i) and (ii) to apply 20 percent stop-loss and stop-gain limits to most CJR-X participants, and our proposal at § 512.650(c)(6)(iii) to apply a 5 percent stop-loss limit to certain categories of CJR-X participants.

#### (h) CJR-X Participant Responsibility for Increased Post-Episode Payments

As we noted in the 2015 CJR final rule that finalized the post-episode spending policy for the CJR Model (80 FR 73398), while the CJR episode extended 90-days post-discharge from the anchor hospitalization, some hospitals may have had an incentive to withhold or delay medically necessary care until after an episode ended to reduce their actual episode payments. We did not believe this would be likely in the CJR Model, especially given the relatively long episode duration, and we continue to believe that this will not be likely in CJR-X. However, in order to identify and address such inappropriate shifting of care, we are proposing to maintain the CJR Model post-episode spending policy in CJR-X. Specifically, we propose to calculate the total Medicare Parts A and B expenditures in the 30-day period following completion of each episode for all services covered under Medicare Parts A and B for each performance year, regardless of whether the services are included in the episode definition proposed in this proposed rule (as discussed in section X.C.2.d.(2). and (3). of this proposed rule). Because we based the episode definition on exclusions, identified by MS-DRGs for readmissions and ICD-10-CM diagnosis codes for Part B services as discussed in section X.C.2.d.(3)(c). of this proposed rule, and Medicare beneficiaries may typically receive a wide variety of related (and unrelated) services during episodes, there is some potential for CJR-X participants to inappropriately

withhold or delay a variety of types of services until the episode concludes regardless of whether the service is included in the episode definition, especially for Part B services where diagnosis coding on claims may be less reliable. This inappropriate shifting could include both those services that are related to the episode (for which the CJR-X participant would bear financial responsibility as they would be included in the actual episode spending calculation) and those that are unrelated (which would not be included in the actual episode spending calculation), because a CJR-X participant engaged in shifting of medically necessary services outside the episode for potential financial benefit may be unlikely to clearly distinguish whether the services were related to the episode or not.

This calculation would include prorated payments for services that extend beyond the episode as discussed in section X.C.2.f.(3)(c). of this proposed rule. Specifically, we would identify whether the average 30-day post-episode spending for a CJR-X participant in any given performance year is greater than three standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all CJR-X participants in the same region. Similar to the CJR Model, post-episode spending would be adjusted for geographic wage factors to express spending in "real" or unstandardized amounts. We propose that if the CJR-X participant's average post-episode spending exceeds this threshold, the CJR-X participant would repay Medicare for the amount that exceeds such threshold. Consistent with the CJR Model, this amount would not be subject to the proposed stop-loss limits discussed in section X.C.2.f.5.(g). of this proposed rule.

We seek comment on our proposal at § 512.650(c)(7) to make CJR-X participants responsible for making repayments to Medicare based on high spending in the 30 days after the end of the episode and for our proposed methodology to calculate the threshold for high post-episode spend.

#### (i) Reconciliation Payments and Repayments

Consistent with the CJR Model, we propose that after subtracting a CJR-X participant's post-episode spending amount from their NPRA as applicable, as described previously in this section, if the resulting amount is positive, the CJR-X participant would receive the amount as a one-time lump sum reconciliation payment from Medicare. If the amount is negative, Medicare

would hold the CJR-X participant responsible for a one-time lump sum repayment. CMS would collect the one-time lump sum repayment in a manner that is consistent with all relevant federal debt collection laws and regulations.

We seek comment on our proposal at § 512.650(d) to make reconciliation payments to, and collect repayment amounts from, CJR-X participants as a one-time, lump sum payment.

#### g. Proposed Appeals Process

##### (1) Notice of Calculation Error and Reconsideration Request

We believe that it is necessary to have a process by which CJR-X participants may appeal the reconciliation report. Therefore, we propose at § 512.660(a) to permit CJR-X participants to submit a notice of calculation error regarding the calculations contained within the CJR-X reconciliation report if the CJR-X participant believes an error occurred in calculations due to data quality or other issues, or if the CJR-X participant believes an error occurred in calculations due to misapplication of methodology. We note that the CJR-X participant would still be subject to the same limitations on review as stipulated at § 512.170. We also propose at § 512.660(b)(1) that if a CJR-X participant believes the CJR-X reconciliation report contains a calculation error, then the CJR-X participant would be required to submit a timely error notice in writing documenting the suspected calculation error within 30 calendar days of issuance of the CJR-X performance report. We also propose that CMS may specify different requirements for the form, manner, or deadline for submission of the error notice. If the CJR-X participant does not provide such timely error notice in accordance with the timelines and processes specified by CMS, then we propose at § 512.660(b)(2) that the CJR-X reconciliation report would be deemed final and the CJR-X participant would be precluded from later contesting those elements of the CJR-X reconciliation report for that performance year. Additionally, we propose that only an CJR-X participant may submit a timely error notice according to the provisions at proposed § 512.660(b)(3).

The proposed 30-day window to review and appeal CMS calculations aligns with the length of time we have finalized for submitting appeals in other mandatory Innovation Center models, such as TEAM, the Ambulatory Specialty Model, and the Increasing Organ Transplant Access Model.

We propose at § 512.660(c) that if CMS receives a timely notice of a calculation error, we would issue an initial determination in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct. We note that CMS would reserve the right to an extension of the time for providing its initial determination upon written notice to the CJR-X participant.

If a CJR-X participant disagrees with and wishes to dispute the results of the initial determination, under proposed § 512.660(d), the CJR-X participant or CMS may request a reconsideration of the initial determination by following the reconsideration review process described in the standard provisions at § 512.190.

We seek comment on our proposed appeals process for CJR-X at § 512.660.

#### h. Concurrent Participation in Other CMS Models and Initiatives

##### (1) Background

When determining the best strategy for addressing concurrent participation in multiple CMS models or initiatives, we recognize we need to consider how to promote meaningful collaboration between providers and CJR-X participants as the model expands. Historically, the overlap policies of CMS Innovation Center models, including the original CJR (80 FR 73274), were intended to avoid duplicative incentive payments or giving precedence to a single accountable entity. However, what resulted were confusing methodologies or misaligned incentives which were difficult to navigate. Participants from prior models have also cited confusion with identifying all of the model(s) to which a beneficiary may be aligned or attributed.

Earlier episode-based payment models, such as the original CJR Model (80 FR 73274) in certain circumstances, and BPCI, are examples of this well-meaning but potentially confusing overlap policy. In these models, CMS addressed overlap by implementing a complex calculation and recouping a portion of the pricing discount for providers also participating in certain ACO initiatives. The recoupment was intended to prevent duplicate incentive payments for the same beneficiary's care; however, some participants perceived the resulting recoupment as a financial loss, discouraging providers from participating in both initiatives. We believe it is important to learn from previous episode-based payment model policies, as discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69786), so that CJR-X can implement a

sustainable long-term policy to account for interactions with other CMS models and initiatives.

##### (2) Beneficiary Participation in Multiple CMS Models or Initiatives

We propose that a beneficiary could be in an episode in CJR-X, as described in section X.C.2.d. of this proposed rule, by undergoing a procedure at an acute care hospital participating in CJR-X, and be attributed to a provider participating in a total cost of care or shared savings model or program. For example, a beneficiary may be attributed to a provider participating in the Shared Savings Program for an entire performance year, as well as having initiated an episode in CJR-X during the ACO's performance year. Each model or program incorporates a reconciliation process, where total included spending during the performance period or episode are calculated, as well as any potential savings achieved by the model or program. We propose to allow any savings generated on an episode in CJR-X and any contribution to savings in the total cost of care model be retained by each respective participant. This would mean the episode spending in CJR-X would be accounted for in the total cost of care model's total expenditures, but CJR-X's reconciliation payment amount or repayment amount would not be included in the total cost of care model's total expenditures. Likewise, the total cost of care model's savings payments or losses would not be included in the episode spending in CJR-X.

This approach deviates slightly from the latter years of the CJR Model, where concurrent participation in total cost of care models was permitted, except for the ENHANCED track of the Medicare Shared Savings Program because the ENHANCED track offered greater financial accountability as compared to the BASIC track or predecessor tracks. As we discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69787), by allowing a beneficiary aligned to a total cost of care model participant, such as the Medicare Shared Savings Program or other ACO initiatives, to also initiate a CJR-X episode, we would be eliminating complexities experienced in prior models where it was difficult for participants to know when a beneficiary would trigger an episode and when the episode would be excluded. Furthermore, this would match the procedure used in newer models such as TEAM, increasing policy design similarity between models. We hope that this uniform decision will increase simplicity. We also believe that allowing concurrent participation for

beneficiaries aligned to a total cost of care model who also initiate an episode in CJR-X and allowing both participants to retain savings will have a positive impact on beneficiaries by fostering a cooperative relationship between accountable care and CJR-X participants where all parties have interest in providing coordinated, longitudinal care.

In addition, there are other potential benefits to allowing overlap between a beneficiary who is aligned to a total cost of care model and who initiates an episode in CJR-X, such as strengthening the volume of episodes a CJR-X participant is responsible for. We know from prior experience that low episode volume creates challenges for participants to generate meaningful savings and manage outlier cases with unusually high episode expenditures. Allowing CJR-X episodes to trigger despite the beneficiary being aligned to a total cost of care model will increase CJR-X episode volume to mitigate these low volume challenges.

We also acknowledge that certain ACOs may prefer that their aligned beneficiary population not be included in CJR-X. Since ACOs are accountable for total cost of care, they may prefer to manage their beneficiaries and have full control over all expenditures and beneficiary care instead of sharing that responsibility with a CJR-X participant. However, we believe the benefits of episode-based payment models in combination with ACO models will ultimately improve Medicare beneficiary care, and episode-based payment models will not be disruptive to ACO practices.

However, we are proposing that CJR-X would not allow for concurrent participation with TEAM. We proposed in section X.C.2.b.(2)(i). of this proposed rule not to allow TEAM participants to be CJR-X participants because TEAM and CJR-X both test bundled payments for LEJRs and are running concurrently. If an LEJR episode occurs at an acute care hospital participating in TEAM, we discussed in section X.C.2.b.(i). of this proposed rule, that TEAM participants would be excluded from CJR-X participation which means that TEAM supersedes the CJR-X model and those LEJR procedures will trigger a TEAM episode rather than a CJR-X episode. Further, we propose at § 512.630(e) that if a beneficiary in a TEAM episode has a LEJR procedure performed at a CJR-X hospital during TEAM's 30-day post-discharge period, then the LEJR procedure will not initiate a CJR-X LEJR episode and the spending from the LEJR procedure will be included in the TEAM episode. We note that while this

instance would result in the CJR-X participant not being attributed the episode, the episode that would have been triggered in CJR-X in the absence of the overlapping TEAM episode would still remain in the national set of episodes used in the calculation of various CJR-X target price components. This is because the national set of LEJR episodes in CJR-X includes all MS-DRG/HCPCS region combinations and therefore all LEJR episodes would need to be retained in the national set. We anticipate this occurrence to be rare given TEAM's shorter post-discharge period and the reduced likelihood that a beneficiary would have another procedure performed within such a short time period if not clinically appropriate. Additionally, in section X.A.2.a.(3). of this proposed rule, we propose that if a beneficiary in a CJR-X episode has a procedure performed at a TEAM hospital that would initiate a TEAM episode during the CJR-X 90-day post-discharge period, then that procedure would not initiate a TEAM episode and the spending from that procedure would be included in the CJR-X episode. We considered giving TEAM precedence in this situation and dropping the CJR-X episode to initiate a TEAM episode to support episode volume in TEAM, but we believe it is important to hold the anchoring provider of the initial procedure accountable for spending and care coordination, especially given the investments that hospitals employ to manage a beneficiary's care. We believe this policy would avoid duplicative calculations for the same procedure in a model that is similar in overall design. We also considered allowing a CJR-X and a non-LEJR TEAM episode to run concurrently. For example, if a beneficiary in a CJR-X episode has a procedure performed at a TEAM hospital during the CJR-X 90-day post-discharge period, then that procedure would initiate a TEAM episode. While we believe this situation would be very rare, we are concerned there could be double payment of savings and may make it difficult to determine which model and hospital were the driver to any realized savings or losses. We are also concerned this situation could make it challenging for the beneficiary to have two accountable episode-based entities potentially providing different guidance on who is managing their care.

We acknowledge there may be new models or programs that could have overlap with CJR-X. This could occur because a beneficiary may trigger an episode in CJR-X while being aligned to a new CMS model or program or

because a CJR-X participant also participates in another CMS model or program. We would plan to assess each new model to determine if the structure of payment and savings calculation would need any additional overlap requirements to account for the new model and would propose a policy in future notice and comment rulemaking, as necessary.

#### i. Financial Arrangements

##### (1) Background

We believe certain financial and beneficiary incentives could help a CJR-X participant reach their quality and efficiency goals under the model and benefit both beneficiaries and the Medicare Trust Fund through reductions in hospital readmissions, complications, days in acute care, and mortality. We also believe there is value in offering flexibilities to CJR-X participants that could support their performance in CJR-X and enable them to meet the needs of beneficiaries. The flexibilities outlined in this section include allowing CJR-X participants to share all or some of their reconciliation payment amount or repayment amount with non-model participants and offer beneficiary incentives to encourage engagement and adherence to recommended treatment throughout recovery.

##### (2) Overview of CJR-X Financial Arrangements

CJR-X participants may wish to enter into financial arrangements with certain providers and suppliers that support CJR-X activities to share their reconciliation payment amount or repayment amount resulting from participation in CJR-X. We believe allowing such arrangements to align financial incentives would support high quality care, improve health outcomes, and reduce Medicare spending through improved beneficiary care transitions and reduced fragmentation following surgery. We expect that CJR-X participants would identify key providers and suppliers caring for beneficiaries in the surrounding communities with whom to establish partnerships to promote accountability for the quality, cost, and overall care for beneficiaries, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigning care processes for high quality and efficient service delivery; and carrying out other obligations or duties under CJR-X.

These providers and suppliers may invest substantial time and other resources in these activities, yet they

would not be the direct recipients of any reconciliation payment amounts or repayment amounts, as they are not the risk bearing entity and do not directly participate in CJR–X. Therefore, we believe it is possible that a CJR–X participant that may receive a reconciliation payment amount or repayment amount may want to enter into financial arrangements with other providers or suppliers to share this reconciliation payment amount or repayment amount with the CJR–X participant. We expect that all financial relationships established between CJR–X participants and providers or suppliers for purposes of CJR–X would be those permitted only under applicable law and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements. As discussed in section X.C.2.i.(9) of this proposed rule, CMS expects, if the proposed arrangements are finalized, to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)) is available to protect certain remuneration proposed in this section when arrangements with eligible providers and suppliers are in compliance with the requirements established in the final rule and the conditions of the safe harbor for CMS-sponsored model arrangements established at 42 CFR 1001.952(ii).

We recognize that there are numerous arrangements that CJR–X participants may wish to enter other than the financial arrangements described in the proposed regulations for which safe harbor protection may be extended that could be beneficial to the CJR–X participants. For example, CJR–X participants may choose to engage with organizations that are neither providers nor suppliers to assist with matters such as data analysis; local provider and supplier engagement; care redesign planning and implementation; beneficiary outreach; beneficiary care coordination and management; monitoring CJR–X participants' compliance with the model's terms and conditions; or other model-related activities. Such organizations may play important roles in a CJR–X participant's plans to implement the model based on the experience these organizations may bring, such as prior experience with episode-based payment models, care coordination expertise, familiarity with a particular local, or knowledge of bundled data. We expect that all relationships established between CJR–X participants and these organizations for purposes of the model would be

those permitted only under existing law and regulation, including any relationships that would include the CJR–X participant's sharing of the reconciliation payment amount or repayment amount. We would expect these relationships to be solely based on the level of engagement of the organization's resources to directly support the CJR–X participants' model implementation.

### (3) CJR–X Collaborators

As proposed, CJR–X is a two-sided financial risk model and the CJR–X participant would bear sole financial risk for any repayment amount to CMS in the absence of financial arrangements. However, given the incentive to reduce episode spending to earn a reconciliation payment amount, as described in section X.C.2.f.(5) of this proposed rule, a CJR–X participant may want to engage in financial arrangements with providers and suppliers or participants in Medicare ACO initiatives who are making contributions to the CJR–X participant's performance in the model. Such arrangements would allow the CJR–X participant to share reconciliation payment amounts or repayment amounts with individuals and entities that have a role in the CJR–X participant's performance in the model. We propose to use the term “CJR–X collaborator” to refer to these individuals and entities.

Because CJR–X participants would be accountable for spending and quality during the anchor hospitalization or anchor procedure and the 90-day post discharge period, as described in section X.C.2.d.(3)(b) of this proposed rule, providers and suppliers other than the CJR–X participant may furnish services to the beneficiary during the model. As such, for purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we propose at § 512.605 to define “CJR–X collaborator” as any of the following types of providers and suppliers that is Medicare-enrolled and eligible to participate in Medicare or entities that are participating in a Medicare ACO initiative may be CJR–X collaborators:

- SNF.
- HHA.
- LTCH.
- IRF.
- Physician.
- Nonphysician practitioner.
- Therapist in a private practice.
- Comprehensive Outpatient Rehabilitation Facility (CORF).
- Provider or supplier of outpatient therapy services.

- Physician Group Practice (PGP).
- Hospital.
- Critical Access Hospital (CAH).
- Non-physician provider group practice (NPPGP).
- Therapy group practice (TGP).
- Medicare ACO.

We seek comment on the proposed definition of “CJR–X collaborator” and any additional Medicare-enrolled providers or suppliers, that should be included in this definition. For example, we considered rural emergency hospitals (REHs), rural clinics, and Federally Qualified Health Centers (FQHCs) because CJR–X would hold CJR–X participants accountable for cost and quality of care during a 90-day episode, and this would include rural beneficiaries that may receive a LEJR procedure. We anticipate rural beneficiaries would receive pre- and post-operative care locally through these sites and allowing these providers to participate in financial arrangements would align incentives across all entities influencing episode outcomes and would encourage better care transitions and follow-up.

### (4) Sharing Arrangements

#### (a) General

Similar to the original CJR Model (42 CFR 510.500), we propose that certain financial arrangements between a CJR–X participant and a CJR–X collaborator be termed “sharing arrangements.” For purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we propose that a sharing arrangement would be to share reconciliation payment amounts or repayment amounts. We propose at to define “sharing arrangement” as a financial arrangement between a CJR–X participant and a CJR–X collaborator for the sole purpose of making gainsharing payments or alignment payments under CJR–X. Where a payment from a CJR–X participant to a CJR–X collaborator is made pursuant to a sharing arrangement, we propose to define that payment as a “gainsharing payment,” which is discussed in section X.C.2.i.(4)(c) of this proposed rule. Where a payment from a CJR–X collaborator to a CJR–X participant is made pursuant to a sharing arrangement, we propose to define that payment as an “alignment payment,” which is discussed in section X.C.2.i.(4)(c) of this proposed rule. A CJR–X participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. We propose that a sharing arrangement

must comply with the provisions of section X.C.2.i.(4)(b) of this proposed rule and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements. We propose that the CJR-X participant and CJR-X collaborator must document this agreement in writing and, per monitoring and compliance guidelines (§ 512.670(b)), the written agreement must be made available to CMS upon request.

We propose that the CJR-X participant must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR-X collaborators. To safeguard against potentially fraudulent or abusive practices, we propose that the selection criteria determined by the CJR-X participant must include the quality of care delivered by the potential CJR-X collaborator. Moreover, the selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the CJR-X participant, any CJR-X collaborator, any collaboration agent, or any individual or affiliated with a CJR-X participant, CJR-X collaborator, or collaboration agent. In addition to including quality of care in their selection criteria, CJR-X participants must also consider selection of CJR-X collaborators based on criteria that include the anticipated contribution to the performance of the CJR-X participant in the model by the potential CJR-X collaborator to ensure that the selection of CJR-X collaborators takes into consideration the likelihood of their future performance.

Finally, we propose that if a CJR-X participant enters a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the model. Requiring oversight of sharing arrangements to be included in the compliance program provides a program integrity safeguard. We note CMS would monitor CJR-X participants for compliance, as permitted under § 512.150, especially if we believe the requirement is not being met as indicated through monitoring activities such as documentation requests, interviews, and site visits.

We seek comment on the proposed “sharing arrangement” definition at § 512.605, the sharing arrangement proposals at § 512.670(a), and whether additional or different safeguards are needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

#### (b) Requirements

We propose several requirements for sharing arrangements to help ensure that their sole purpose is to create financial alignment between CJR-X participants and CJR-X collaborators toward the goals of the model while maintaining adequate program integrity safeguards. We propose that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to CJR-X beneficiaries under the sharing arrangement. In addition, participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. It is important that providers and suppliers rendering items and services to beneficiaries during the model have the freedom to provide medically necessary items and services to beneficiaries without any requirement that they participate in a sharing arrangement to safeguard beneficiary freedom of choice, access to care, and quality of care. The sharing arrangement must set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward model care redesign for future performance toward model goals, rather than reflect the results of model performance years that have already occurred and where the financial outcome of the sharing arrangement terms would be known before signing.

We propose that the sharing arrangement must require the CJR-X collaborator and its employees, contractors, and subcontractors to comply with certain requirements that are important for program integrity under the arrangement. We note that the terms contractors and subcontractors include collaboration agents as defined later in this section. The sharing arrangement must require all of the individuals and entities party to the arrangement to comply with the applicable provisions of this proposed rule, including proposed requirements regarding beneficiary notifications, at proposed § 512.622(b), and access to records and record retention and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees, in accordance with the standard provisions for Innovation Center models at § 512.135, because these individuals and entities all would play a role in model care redesign and be part of financial arrangements under the model as proposed. The sharing arrangement must also require all individuals and entities party to the arrangement who are providers or suppliers to comply

with the applicable Medicare provider enrollment requirement at § 424.500, including having a valid and active TIN or NPI, during the term of the sharing arrangement. This proposed requirement is to ensure that the individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we note that they are not responsible for complying with requirements that do not apply to them. Finally, the sharing arrangement must require individuals and entities to comply with all other applicable laws and regulations.

We propose that the sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between CJR-X participants and CJR-X collaborators do not negatively impact beneficiary protections under the model. The sharing arrangement as proposed must require the CJR-X collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the model, just as we require CJR-X participants to have a compliance program that covers oversight of the sharing arrangement for this purpose as a program integrity safeguard. We seek comment on the anticipated effect of the proposed compliance program requirement for CJR-X collaborators, particularly with regard to individual physicians and nonphysician practitioners, small PGPs, NPPGPs, and TGPs and whether alternative compliance program requirements for all or a subset of CJR-X collaborators should be adopted to mitigate any effect of the proposal that could make participation as a CJR-X collaborator infeasible for any provider, supplier, or other entity on the proposed list of types of CJR-X collaborators.

It is necessary that CJR-X participants have adequate oversight over sharing arrangements to ensure that all arrangements meet the requirements of this section and provide program integrity protections. Therefore, we propose that the board or other governing body of the CJR-X participant have responsibility for overseeing the CJR-X participant's participation in the model, its arrangements with CJR-X collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the model. Additionally, we propose that the CJR-X participant and CJR-X collaborator must document this agreement in writing and, as part of the model's monitoring and compliance activities as proposed in

(§ 512.670(b)(7)), we propose that this agreement must be made available to CMS upon request.

For purposes of sharing arrangements under the model, we propose at § 512.605 to define “CJR–X activities” as activities related to promoting accountability for the quality, cost, and overall care for CJR–X beneficiaries and performance in the model, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty under the model. In addition to the quality of care provided during episodes, we believe the activities that would fall under this proposed definition encompass the totality of activities upon which it would be appropriate for sharing arrangements under the model to be based in order to value the contributions of providers, suppliers, and other entities toward meeting the performance goals of the model. We seek comment on the proposed definition of “CJR–X activities” as an inclusive and comprehensive framework for capturing direct care and care redesign that contribute to performance toward model goals.

We propose that the written agreement memorializing a sharing arrangement must specify the following parameters of the arrangement:

- The purpose and scope of the sharing arrangement.
- The identities and obligations of the parties, including specified CJR–X activities and other services to be performed by the parties under the sharing arrangement.
- The date of the sharing arrangement.
- Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out CJR–X activities.
- The financial or economic terms for payment, including the following:
  - ++ Eligibility criteria for a gainsharing payment.
  - ++ Eligibility criteria for an alignment payment.
  - ++ Frequency of gainsharing or alignment payment.
  - ++ Methodology and accounting formula for determining the amount of a gainsharing payment that is solely based on quality of care and the provision of CJR–X activities.
  - ++ Methodology and accounting formula for determining the amount of an alignment payment.

Finally, we propose to require that the terms of the sharing arrangement must

not induce the CJR–X participant, CJR–X collaborator, or any employees, contractors, or subcontractors of the CJR–X participant or CJR–X collaborator to reduce or limit medically necessary services to any beneficiary or restrict the ability of a CJR–X collaborator to make decisions in the best interests of CJR–X beneficiaries, including the selection of devices, supplies, and treatments. These requirements are to ensure that the quality of care for beneficiaries is not negatively affected by sharing arrangements under the model.

We seek comment on the “CJR activities” definition and the sharing arrangement requirements at § 512.670.

#### (c) Gainsharing Payment and Alignment Payment Conditions and Limitations

We propose several conditions and limitations for gainsharing payments and alignment payments as program integrity protections for the payments to and from CJR–X collaborators. We propose to require that gainsharing payments be derived solely from a CJR–X participant’s reconciliation payment amounts, internal costs savings, or both; that they be distributed on an annual basis, not more than once per calendar year; that they not be a loan, advance payment, or payment for referrals or other business; and that they be clearly identified as a gainsharing payment at the time they are paid.

We believe that gainsharing payment eligibility for collaborators should be conditioned on two requirements—(1) quality of care criteria; and (2) the provision of CJR–X activities. With respect to the first requirement, we propose that to be eligible to receive a gainsharing payment, the collaborator must meet quality of care criteria during the performance year for which the participant earned a reconciliation payment amount that comprises the gainsharing payment. We propose that these quality of care criteria will be included in the sharing arrangement and mutually agreed upon by the CJR–X participant and CJR–X collaborator. With regard to the second requirement, to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a collaborator other than a PGP, NPPGP, or TGP must have directly furnished a billable item or service to a beneficiary during the same performance year for which the participant earned a reconciliation payment amount or repayment amount. For purposes of this requirement, we consider a hospital, CAH or post-acute care provider to have “directly furnished” a billable service if one of these entities billed for an item or service for a CJR–X beneficiary in the

performance year for which the CJR–X participant earned a reconciliation payment amount or repayment amount. The phrase “episode” refers to all Part A and B items and services described in section X.C.2.d.(3)(b) of this proposed rule (excluding the items and services described in section X.C.2.d.(3)(c)) of this proposed rule that are furnished to a beneficiary described in section X.C.2.c of this proposed rule. During the time period that begins with the beneficiary’s admission to an anchor hospitalization or the date of the anchor procedure, as applicable, and ends on the 90th day of either the date of discharge from the anchor hospitalization or the date of service for the anchor procedure. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the direct care for CJR–X beneficiaries during an episode for these CJR–X collaborators. We believe the provision of direct care is essential to the implementation of effective care redesign, and the requirement provides a safeguard against payments to CJR–X collaborators other than a PGP, NPPGP, or TGP that are unrelated to direct care for CJR–X beneficiaries during the model’s performance year.

We propose to establish similar requirements for PGPs, NPPGPs and TGPs that vary because these entities do not themselves directly furnish billable services. To be eligible to receive a gainsharing payment or required to make an alignment payment for a given performance year, a PGP, NPPGP or TGP must have billed for an item or service that was rendered by one or more members of the PGP, NPPGP or TGP to a CJR–X beneficiary during the episode that is attributed to the same performance year for which the CJR–X participant earned a reconciliation payment amount or repayment amount. Like the proposal for CJR–X collaborators that are not PGPs, these proposals also require a link between the CJR–X collaborator that is the PGP, NPPGP or TGP and the provision of items and services to beneficiaries during the episode by PGP, NPPGP or TGP members.

Moreover, we further propose that, because PGPs, NPPGPs and TGPs do not directly furnish items and services to beneficiaries, in order to be eligible to receive a gainsharing payment or be required to make an alignment payment, for a given performance year the PGP, NPPGP or TGP must have contributed to CJR–X activities and been clinically involved in the care of beneficiaries during an episode that is attributed to the same performance year for which

the CJR–X participant earned a reconciliation payment amount or repayment amount that comprises the gainsharing payment.

We propose that the amount of any gainsharing payments must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities. We considered whether this methodology could substantially, rather than solely, be based on quality of care and the provision of CJR–X but ultimately determined that basing the methodology solely on these two elements creates a model safeguard where gainsharing aligns directly with the model goal of quality of care and with CJR–X activities. The gainsharing methodology may take into account the amount of such CJR–X activities provided by a CJR–X collaborator relative to other CJR–X collaborators. While we emphasize that financial arrangements may not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among CJR–X participants, any CJR–X collaborator, any collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, or collaboration agent so that their sole purpose is to align the financial incentives of the CJR–X participant and CJR–X collaborators toward the model, we believe that accounting for the relative amount of CJR–X activities by CJR–X collaborators in the determination of gainsharing payments does not undermine this objective. Rather, the proposed requirement allows flexibility in the determination of gainsharing payments where the amount of a CJR–X collaborator's provision of CJR–X activities (including direct care) to CJR–X beneficiaries during a performance year may contribute to the CJR–X participant's reconciliation payment amount that may be available for making a gainsharing payment. Greater contributions of CJR–X activities by one CJR–X collaborator versus another CJR–X collaborator that result in greater differences in the funds available for gainsharing payments may be appropriately valued in the methodology used to make gainsharing payments to those CJR–X collaborators in order to reflect these differences in CJR–X activities among CJR–X collaborators.

However, we do not believe it would be appropriate to allow the selection of CJR–X collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment to take into account the amount of CJR–X activities provided by a potential or

actual CJR–X collaborator relative to other potential or actual CJR–X collaborators because these financial relationships are not to be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, or collaboration agent. Specifically, with respect to the selection of CJR–X collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment, we do not believe that the amount of model activities provided by a potential or actual CJR–X collaborator relative to other potential or actual CJR–X collaborators could be taken into consideration by the CJR–X participant without a significant risk that the financial arrangement in those instances could be based directly or indirectly on the volume or value of referrals or business generated by, between or among the parties. Similarly, if the methodology for determining alignment payments was allowed to take into account the amount of CJR–X activities provided by a CJR–X collaborator relative to other CJR–X collaborators there would be a significant risk that the financial arrangement could directly account for the volume or value of referrals or business generated by, between or among the parties and, therefore, we propose that the methodology for determining alignment payments may not directly take into account the volume or value of referrals or business generated by, between or among the parties.

We also considered whether the methodology for gainsharing payments should be based substantially on quality of care and the provision of CJR–X activities, rather than solely on these two elements and whether the methodology could take into account the amount of CJR–X activities provided by a CJR–X collaborator relative to other CJR–X collaborators. We were particularly interested in whether this standard would provide sufficient additional flexibility in the gainsharing payment methodology to allow the financial reward of CJR–X collaborators commensurate with their level of effort that achieves model goals. Ultimately, we are proposing to follow the CJR Model and TEAM gainsharing methodologies.

We propose that for each performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment amount by the CJR–X participant must not

exceed the amount of the reconciliation payment amount. In accordance with the prior discussion, no entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, or collaboration agent. We propose that a CJR–X participant must not make a gainsharing payment to a CJR–X collaborator that is subject to any action for noncompliance by CMS or any other federal or state entity or subject to noncompliance with any other federal or state laws or regulations, or for the provision of substandard care to beneficiaries or other integrity problems. Finally, the sharing arrangement must require the CJR–X participant to recover any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation payment amount or was based on the submission of false or fraudulent data. These requirements provide program integrity safeguards for gainsharing under sharing arrangements.

With respect to alignment payments, we propose that alignment payments from a CJR–X collaborator to a CJR–X participant may be made at any interval that is agreed upon by both parties. Alignment payments must not be issued, distributed, or paid prior to the calculation by CMS of the repayment amount, and cannot be assessed in the absence of a repayment amount. The CJR–X participant must not receive any amounts under a sharing arrangement from a CJR–X collaborator that are not alignment payments.

We also propose certain limitations on alignment payments that are consistent with the CJR Model. For a performance year, the aggregate amount of all alignment payments received by the CJR–X participant from all of the CJR–X participant's CJR–X collaborators must not exceed 50 percent of the repayment amount. Given that the CJR–X participant would be responsible for developing and coordinating care redesign strategies in response to its CJR–X participation, we believe it is important that the CJR–X participant retain a significant portion of its responsibility for repayment amounts. In addition, the aggregate amount of all alignment payments from a CJR–X collaborator to the CJR–X participant for a CJR–X collaborator other than an ACO



may not be greater than 25 percent of the CJR–X participant’s repayment amount. The aggregate amount of all alignment payments from a CJR–X collaborator to the CJR–X participant for a CJR–X collaborator that is an ACO may not be greater than 50 percent of the CJR–X participant’s repayment amount.

We propose that all gainsharing payments and any alignment payments must be administered by the CJR–X participant in accordance with GAAP and Government Auditing Standards (The Yellow Book). Additionally, we propose that all gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction. We make this proposal to mitigate the administrative burden that the electronic fund transfer (EFT) requirement would place on the financial arrangements between certain CJR–X participants and CJR–X collaborators, especially individual physicians and nonphysician practitioners and small PGPs, NPPGPs or TGP members which could discourage participation of those suppliers as CJR–X collaborators.

We seek comment on our proposals at § 512.670(c) on the conditions and restrictions on gainsharing payments, alignment payments, and internal cost savings under the model.

#### (d) Documentation Requirements

To ensure the integrity of the sharing arrangements, we propose that CJR–X participants must meet a variety of documentation requirements for these arrangements. Specifically, the CJR–X participant must—

- Document the sharing arrangement contemporaneously with the establishment of the arrangement;
- Maintain accurate current and historical lists of all CJR–X collaborators, including CJR–X collaborator names and addresses; update such lists on at least a quarterly basis; and publicly report the current and historical lists of CJR–X collaborators on the CJR–X participant’s website; and
- Maintain and require each CJR–X collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the—

- ++ Nature of the payment (gainsharing payment or alignment payment);
- ++ Identity of the parties making and receiving the payment;
- ++ Date of the payment;

- ++ Amount of the payment;
- ++ Date and amount of any recoupment of all or a portion of a CJR–X collaborator’s gainsharing payment; and

++ Explanation for each recoupment, such as whether the CJR–X collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of a reconciliation payment amount, or was based on the submission of false or fraudulent data.

In addition, we propose that the CJR–X participant must keep records for all of the following:

- A process for determining and verifying potential and current CJR–X collaborators’ eligibility to participate in Medicare if the CJR–X collaborator is a Medicare-enrolled provider or supplier.
- A plan to track internal cost savings.
- Information on the accounting systems used to track internal cost savings.
- A description of current health information technology, including systems to track reconciliation payment amounts, repayment amounts, and internal cost savings.
- A plan to track gainsharing payments and alignment payments.

Finally, we propose that the CJR–X participant must retain and provide access to, and must require each CJR–X collaborator to retain and provide access to, the required documentation in accordance with § 512.135 and 42 CFR 1001.952(ii).

We seek comment on our proposals on the documentation requirements for sharing arrangements at § 512.670(d). We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

#### (5) Distribution Arrangements

##### (a) General

Similar to the CJR Model (80 FR 73541), we propose that certain financial arrangements between CJR–X collaborators and other individuals or entities called “collaboration agents” be termed “distribution arrangements.” In the January 2017 CJR final rule (82 FR 180), we finalized a full replacement of the prior CJR Model regulations to allow for—(1) participant hospitals to enter into sharing arrangements with additional categories of CJR collaborators, including certain ACOs, hospitals, CAHs, NPPGPs and therapy group practices (TGPs); (2) ACOs, PGPs, NPPCGs and TGPs that are CJR

collaborators to enter into distribution arrangements with certain entities and individuals; and (3) PGPs, NPPGPs and TGPs that received distribution payments from ACOs to enter into downstream distribution arrangements to share distribution payments with certain of their members. Similarly in CJR–X, a “collaboration agent” would be defined as an individual or entity that is not a CJR–X collaborator and that is a PGP, NPPGP, or TGP member that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee. For purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we propose that a “distribution arrangement” would be defined as a financial arrangement between a CJR–X collaborator that is a PGP, NPPGP or TGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the PGP, NPPGP or TGP. Where a payment from a CJR–X collaborator to a collaboration agent is made pursuant to a CJR–X distribution arrangement, we define that payment as a “distribution payment.” A collaboration agent may only make a distribution payment in accordance with a distribution arrangement which complies with the provisions of this proposed model and all other applicable laws and regulations, including the fraud and abuse laws.

Like our proposal for gainsharing payments, we propose that the amount of any distribution arrangements must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities. We considered whether this methodology could substantially, rather than solely, be based on quality of care and the provision of CJR–X activities, but ultimately determined that basing the methodology solely on these two elements creates a model safeguard where gainsharing aligns directly with the model goal of quality of care and with CJR–X activities.

We seek comment on our definitions for “collaboration agent,” “distribution arrangements,” and “distribution payment” at § 512.605. We also seek comment on our distribution arrangements proposals at § 512.675(a).

##### (b) Requirements

We propose several requirements to help ensure that the sole purpose of distribution arrangements is to create financial and CJR–X performance alignment between CJR–X collaborators and collaboration agents. These requirements largely parallel those



proposed in section X.C.2.i.(4)(b) of this proposed rule for sharing arrangements and gainsharing payments. We propose that all distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to CJR–X beneficiaries under the distribution arrangement. Furthermore, we propose that participation must be voluntary and without penalty for nonparticipation, and the distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

We propose that any distribution payments must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities. We propose that the opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, or collaboration agent. We propose more flexible standards for the determination of the amount of distribution payments from PGPs, NPPGPs and TGP's allowing CJR–X collaborators and collaboration agents to create tailored distribution payments that supports the individual structure of their arrangement.

We note that for distribution payments made by a PGP to PGP members, by NPPGP's to NPPGP members, or TGP's to TGP members, the requirement that the amount of any distribution payments must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities may be more limiting in how a PGP, NPPGP or TGP pays its members than is allowed under existing law. However, we believe quality of care is an important facet of episode-based payment models and making this a requirement for distribution payment supports greater emphasis on quality of care improvement in CJR–X. Further this is consistent with the BPCI Advanced model that required their NPRA Shared Payments and Partner Distribution Payments to achieve quality performance targets to receive these payments.

We seek comment on this proposal and specifically whether there are additional safeguards or a different standard is needed to allow for greater flexibility in calculating the amount of distribution payments that would avoid

program integrity risks and whether additional or different safeguards are reasonable, necessary, or appropriate for the amount of distribution payments from a PGP to its members, a NPPGP to its members or a TGP to its members.

Similar to our proposed requirements for sharing arrangements for those CJR–X collaborators that furnish or bill for items and services, we propose that a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to a beneficiary during an episode that occurred during the same performance year for which the CJR–X participant accrued the internal cost savings or earned a reconciliation payment amount that comprises the gainsharing payment being distributed. We note that all individuals and entities that fall within our proposed definition of collaboration agent may either directly furnish or bill for items and services rendered to beneficiaries. This proposal ensures that there is the same required relationship between direct care for CJR–X beneficiaries during a performance year and distribution payment eligibility that we require for gainsharing payment eligibility. We believe this requirement provides a safeguard against payments to collaboration agents that are unrelated to direct care for CJR–X beneficiaries during the performance year.

We further propose that with respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP or TGP, the total amount of all distribution payments in a performance year must not exceed the amount of the gainsharing payment received by the CJR–X collaborator from the CJR–X participant for that performance year. Like gainsharing and alignment payments, we propose that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The collaboration agent must retain the ability to make decisions in the best interests of the CJR–X beneficiary, including the selection of devices, supplies, and treatments. Finally, the distribution arrangement must not induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the CJR–X collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.675(b), including—

- The relevant written agreements;

- The date and amount of any distribution payment(s);
- The identity of each collaboration agent that received a distribution payment; and
- A description of the methodology and accounting formula for determining the amount of any distribution payment.

We propose that the CJR–X collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same CJR–X participant, which is continuation of the CJR Model policy in the 2015 final rule (80 FR 73427). This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment and distribution payment to PGPs, NPPGP's, TGP's, physicians, and nonphysician practitioners that are solely based on quality of care and the provision of CJR–X activities are not exceeded in absolute dollars by a PGP, NPPGP, TGP, physician, or nonphysician practitioner's participation in both a sharing arrangement and distribution arrangement for the care of the same CJR–X beneficiaries during the performance year. Allowing both types of arrangements for the same individual or entity for care of the same beneficiary during the performance year could also allow for duplicate counting of the individual or entity's same contribution toward model goals and provision of CJR–X activities in the methodologies for both gainsharing and distribution payments, leading to financial gain for the individual or entity that is disproportionate to the contribution toward model goals and provision of CJR–X activities by that individual or entity. However, we recognize there could be instances where an individual or entity could have distribution arrangements with multiple CJR–X collaborators. For example, a physician may practice with and have reassigned their Medicare billing rights to multiple PGPs, and those PGPs may each be CJR–X collaborators. We seek comment on allowing an individual or entity to have distribution arrangements with multiple CJR–X collaborators and whether there are additional program integrity safeguards that should be established in those scenarios. Finally, we propose that the CJR–X collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation.

We seek comment on the requirements for distribution arrangements under CJR–X at § 512.675(b)

## (6) Downstream Distribution Arrangements

### (a) General

We propose that CJR–X allow for certain financial arrangements within an ACO between a PGP and its members. Specifically, we propose that certain financial arrangements between a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant and another individual termed “downstream collaboration agent” be termed a “downstream distribution arrangement.” We propose to define a “downstream distribution arrangement” as a financial arrangement between a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP, NPPGP, or TGP. We propose to define a “downstream collaboration agent” as an individual who is not a CJR–X collaborator or a collaboration agent and who is a PGP member, a NPPGP member, or a TGP member that has entered into a downstream distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a collaboration agent. Where a payment from a collaboration agent to a downstream collaboration agent is made pursuant to a downstream distribution arrangement, we define that payment as a “downstream distribution payment.” A collaboration agent may only make a downstream distribution payment in accordance with a downstream distribution arrangement which complies with the requirements of this section and all other applicable laws and regulations, including the fraud and abuse laws.

We seek comment on the definitions at § 512.605 for “downstream collaboration agent,” “downstream distribution arrangement,” and “downstream distribution payment.”

### (b) Requirements

To help ensure that the sole purpose of downstream distribution arrangements is to create financial alignment between collaboration agents that are PGPs, NPPGPs, or TGPs which are also ACO participants and downstream collaboration agents and to meet the quality and efficiency goals of CJR–X We propose that all downstream distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and entered into before care is furnished to CJR–X beneficiaries under the downstream distribution

arrangement. Furthermore, we propose that participation must be voluntary and without penalty for nonparticipation, and the downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

Like our proposals for gainsharing and distribution payments, we propose that the opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent. We propose the amount of any downstream distribution payments from an NPPGP to an NPPGP member or from a TGP to a TGP member must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities and that may take into account the amount of such CJR–X activities provided by a downstream collaboration agent relative to other downstream collaboration agents. We believe that the amount of a downstream collaboration agent’s provision of CJR–X activities (including direct care) to CJR–X beneficiaries during episodes may contribute to the CJR–X participant’s internal cost savings and reconciliation payment amount that may be available for making a gainsharing payment to the CJR–X collaborator that is then shared through a distribution payment to the collaboration agent with which the downstream collaboration agent has a downstream distribution arrangement. Greater contributions of CJR–X activities by one downstream collaboration agent versus another downstream collaboration agent that result in different contributions to the distribution payment made to the collaboration agent with which the downstream collaboration agents both have a downstream distribution arrangement may be appropriately valued in the methodology used to make downstream distribution payments to those downstream collaboration agents.

Similar to our proposed requirements for distribution arrangements for those CJR–X collaborators that are PGPs, we propose that a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream

collaboration agent to a CJR–X beneficiary during an episode that was attributed to the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant. This proposal ensures that there is the same required relationship between direct care for CJR–X beneficiaries during episodes and downstream distribution payment eligibility that we require for gainsharing and distribution payment eligibility. We believe this requirement provides a safeguard against payments to downstream collaboration agents that are unrelated to direct care for CJR–X beneficiaries during episodes.

Further, we propose that the total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the collaboration agent (that is, the PGP, NPPGP, or TGP that is an ACO participant) from the ACO that is a CJR–X collaborator. Like gainsharing, alignment, and distribution payments, we propose that all downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The downstream collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments. The distribution arrangement must not induce a downstream collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the PGP, NPPGP, or TGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.680(b)(12), including all of the following:

- The relevant written agreements.
- The date and amount of any downstream distribution payment(s).
- The identity of each downstream collaboration agent that received a downstream distribution payment.
- A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

We propose that the PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP, NPPGP, or TGP member who has a sharing arrangement with a CJR–X participant or distribution arrangement

with the ACO the PGP, NPPGP, or TGP is a participant in. This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment, distribution payment, and downstream distribution payment to PGP, NPPGP, or TGP members that are solely based on quality of care and the provision of CJR–X activities are not exceeded in absolute dollars by a PGP, NPPGP, or TGP member's participation in more than one type of arrangement for the care of the same CJR–X beneficiaries during episodes. Allowing more than one arrangement for the same PGP, NPPGP, or TGP member for the care of the same CJR–X beneficiaries during episodes could also allow for duplicate counting of the PGP, NPPGP, or TGP member's effort in CJR–X activities in the methodologies for the different payments. Finally, we propose that the PGP, NPPGP, or TGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.680(b)(14).

We seek comment on the requirements for downstream distribution arrangements at § 512.680.

#### (7) Beneficiary Incentives

We believe it is necessary and appropriate to provide additional flexibilities to CJR–X participants to increase access to tools that could improve CJR–X beneficiaries' quality of care and meet other goals of the model. CJR–X participants may choose to provide in-kind patient engagement incentives to CJR–X beneficiaries in an episode, which may include, but would not be limited to, items of technology, subject to the following conditions consistent with 42 CFR 510.515.

As discussed in section X.C.2.i.(9) of this proposed rule, if the proposed beneficiary incentives are finalized, we would expect to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)) is available to protect the beneficiary incentives proposed in this section when the incentives are offered in compliance with the requirements established in the final rule and the conditions for use of the anti-kickback statute safe harbor set out at 42 CFR 1001.952(ii).

As stated previously, CJR–X participants may choose to provide in-kind engagement incentives, which may include but not be limited to items of technology, to CJR–X beneficiaries in an episode, subject to the following proposed conditions. We propose that

the incentive must be provided directly by the CJR–X participant or by an agent of the CJR–X participant under their direction and control to the CJR–X beneficiary during an episode.

Additionally, we propose that the item or service provided must be reasonably connected to the CJR–X beneficiary's medical care, and be a preventive care item or service or an item of service that advances a clinical goal, as described in section X.C.2.i.(7)(b) of this proposed rule, by engaging the CJR–X beneficiary in better managing their own health.

We seek comment on the proposed conditions for CJR–X beneficiary incentives, as outlined in § 512.685. Specifically, we seek comment on whether these proposed conditions are reasonable, and whether additional conditions are appropriate to further engage CJR–X beneficiaries in their own healthcare management while preventing fraud or abuse.

#### (a) Technology Provided to a CJR–X Beneficiary

In some cases, items or services involving technology may be useful as beneficiary engagement incentives that can advance a clinical goal of CJR–X by engaging a CJR–X beneficiary in managing their health during the 90 days following discharge from the anchor hospitalization or anchor procedure. However, we believe specific enhanced safeguards are necessary for these items and services to prevent abuse, and our proposals are consistent with the CJR Model policies (80 FR 73437). Specifically, we propose that items or services involving technology provided to a beneficiary may not exceed \$1,000 in retail value for any CJR–X beneficiary in any episode (per episode), and that items or services involving technology provided to a CJR–X beneficiary must be the minimum necessary to advance a clinical goal as discussed in this section for a CJR–X beneficiary in an episode. We propose additional enhanced requirements for items of technology exceeding \$75 in retail value as an additional safeguard against misuse of these items as beneficiary engagement incentives. Specifically, we propose that these items of technology that exceed \$75 in retail value remain the property of the CJR–X participant and be retrieved from the CJR–X beneficiary at the end of the episode. The CJR–X participant must document all retrieval attempts, including the ultimate date of retrieval. We understand that CJR–X participants may not always be able to retrieve these items after the episode ends, such as when a CJR–X beneficiary dies or moves to another geographic area. Therefore, in

cases when the item of technology is not able to be retrieved, the CJR–X participant must determine why the item was not retrievable and if it was determined that the item was used inappropriately (if it were sold, for example) preventing future beneficiary incentives for that CJR–X beneficiary. Following this process, the documentation of diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement. We recognize this requirement may increase CJR–X participant burden to document attempts at retrieval and seek comment if the value threshold should be raised or if there are other ways to demonstrate attempts at retrieval that may be less burdensome for the CJR–X participant.

We seek comment on our proposed CJR–X requirements at § 512.685 for beneficiary engagement incentives that involve technology. We welcome comment on additional or alternative program integrity safeguards for this type of beneficiary engagement incentive, including whether the financial thresholds proposed in this section are reasonable, necessary, and appropriate.

#### (b) Clinical Goals of CJR–X

As discussed in section X.C.2.d. of this proposed rule, the proposed “episodes” are broadly defined to include most Part A and Part B items and services furnished during episodes of care that extend 90 days following discharge from the anchor hospitalization or anchor procedure that begins the episode. Therefore, we believe that in-kind beneficiary engagement incentives may appropriately be provided for managing acute conditions arising from episodes, as well as chronic conditions if the condition is likely to have been affected by care during the episode or when substantial services are likely to be provided for the chronic condition during the episode. We are proposing to allow CJR–X participants to offer in-kind beneficiary engagement incentives, where such incentives must be closely related to the provision of high-quality care and advance a clinical goal for a CJR–X beneficiary and should not serve as inducements for CJR–X beneficiaries to seek care from the CJR–X participants or other specific suppliers and providers. This outline is similar to the beneficiary incentive guidelines outlined previously in the CJR Model (80 FR 73553). We propose that beneficiary incentives must advance one of the following clinical goals of CJR–X:

- Beneficiary adherence to drug regimens.

- Beneficiary adherence to a care plan.
- Reduction of readmissions and complications resulting from treatment during the episode.
- Management of chronic diseases and conditions that may be affected by treatment for the CJR–X clinical condition.

We seek comment on our proposals for beneficiary engagement incentives at § 512.685.

#### (c) Documentation of Beneficiary Engagement Incentives

As a program safeguard against misuse of beneficiary engagement incentives under CJR–X, we propose that CJR–X participants must maintain documentation of items and services furnished as beneficiary engagement incentives that exceed \$25 in retail value including items of technology. In addition, we propose to require that the documentation established contemporaneously with the provision of the items and services must include at least the following:

- The date the incentive is provided.
- The incentive and estimated value of the item or service.
- The identity of the beneficiary to whom the item or service was provided.

We further propose that the documentation regarding items of technology exceeding \$75 in retail that are required to be retrieved from the beneficiary at the end of an episode must also include contemporaneous documentation of any attempt to retrieve technology. In instances where the item of technology is not able to be retrieved, the CJR–X participant must determine why it is not retrievable, and if the item were misappropriated (if it were sold, for example), then further steps must be taken to ensure that CJR–X beneficiary does not receive further beneficiary incentives. Following this process, documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement. This outline is similar to the beneficiary incentive guidelines outlined previously in the CJR Model (80 FR 73553).

Finally, we propose that the CJR–X participant must retain and provide access to the required documentation in accordance with § 512.135.

We seek comment on our proposed documentation requirements for beneficiary engagement incentives under CJR–X at § 512.685(d).

#### (8) Enforcement Authority

OIG authority is not limited or restricted by the provisions of the model, including the authority to audit,

evaluate, investigate, or inspect the CJR–X participant, CJR–X collaborators, collaboration agents, downstream collaboration agents, or any other person or entity or their records, data, or information, without limitations. Additionally, no model provisions limit or restrict the authority of any other Government Agency to do the same.

The propose that the enforcement authority for CJR–X would be in accordance with the standard provisions applicable to all Innovation Center models at § 512.160.

#### (9) Fraud and Abuse Waiver and OIG Safe Harbor Authority

Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii) of the Act, and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

In the CJR 2015 final rule (80 FR 73325) the model was delayed by 3 months to allow for adequate time to prepare for hospital participation. Under the authority in the previous paragraph, OIG and CMS jointly issued Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model (hereinafter “CJR 2017 notice”) effective January 1, 2018.<sup>483</sup> The CJR 2017 notice set forth the specific conditions that must be met by CJR Model participants to qualify for a waiver. The waivers in the CJR 2017 Notice protected specific financial arrangements that were entered into pursuant only to the CJR Model and described in the regulations governing the CJR Model at 42 CFR part 510, as amended from time to time.<sup>484</sup> The waivers in the CJR 2017 notice did not apply to other arrangements that may be entered into by participant hospitals and other entities or individuals and were not applicable outside of the CJR Model. These notices waived section 1128A(a)(5) of the Act (relating to the beneficiary inducements civil monetary penalty (CMP) law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) under section 1115A(d)(1) of the Act

with respect to specified arrangements permitted under the CJR Model.

For this model and consistent with the authority under section 1115A(d)(1) of the Act, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. No fraud or abuse waivers are being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Any such waiver would apply solely to CJR–X, as done under the CJR Model, and could differ in scope or design from waivers granted for other programs or models. Thus, notwithstanding any provision of this proposed rule, CJR–X participants, CJR–X collaborators, collaboration agents, and downstream collaboration agents must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to section 1115A(d)(1) of the Act specifically for CJR–X.

In addition to or in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(1) and 42 CFR 1001.952(ii)(2)) is available to protect remuneration exchanged pursuant to certain financial arrangements and patient incentives that may be permitted under the final rule, if issued. Specifically, if the proposed rule is finalized, we expect to determine that the CMS-sponsored models safe harbor will be available to protect the following financial arrangements and incentives: the CJR–X sharing arrangement’s gainsharing payments and alignment payments, the distribution arrangement’s distribution payments with CJR–X collaborators and collaboration agents, the downstream distribution arrangements and downstream distribution payments with collaboration agents and downstream collaboration agents, and CJR–X beneficiary incentives. At proposed § 512.690(a), we propose to make the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements available to protect remuneration furnished in the CJR–X in the form of the sharing arrangement’s gainsharing payments and alignment payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and proposed § 512.670, in the form of the distribution arrangement’s distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and proposed § 512.675,

<sup>483</sup> The CJR 2017 Notice is available at: <https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/downloads/2017-cjr-model-waivers.pdf>.

<sup>484</sup> See 80 FR 73274 (November 24, 2015), as amended by 82 FR180 (January 3, 2017) and 82 FR 57066 (December 1, 2017).

and in the form of the downstream distribution arrangement's distribution payments provided that all of the financial arrangements associated with such payment meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and proposed § 512.680.

Additionally, at proposed § 512.690(b), we propose to make the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) available to protect CJR-X beneficiary incentives that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and 512.685.

We seek comment on our proposals at § 512.690 that the anti-kickback safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) and CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) be available to CJR-X participants and CJR-X collaborators, collaboration agents, and downstream collaboration agents.

#### j. Proposed Waivers of Medicare Program Requirements

##### (1) Overview

We believe it may be necessary and appropriate to provide flexibilities to hospitals participating in CJR-X, as well as other providers and suppliers that furnish services to beneficiaries in episodes. The purpose of such flexibilities would be to increase episode quality, decrease episode spending or internal costs, or both of providers and suppliers, resulting in better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, and beneficiaries. These waivers were conducted in the CJR Model, and the easing of rules around the 3-Day SNF Rule and Telehealth allowed for easier discharges to less intensive settings and to avoid any resulting drops in quality of care via unplanned readmissions. These possible additional flexibilities could include use of our waiver authority under section 1115A of the Act, which provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act.

As we have stated elsewhere in section X.C.1.c. of this proposed rule, our previous and current efforts in

testing episode-based-payment models have led us to believe that models where entities bear financial responsibility for total Medicare spending for episodes of care hold the potential to incentivize the most substantial improvements in episode quality and efficiency. We believe that where CJR-X participants bear financial accountability for excess episode spending beyond the reconciliation target price while high quality care is valued, they will have an increased incentive to coordinate care furnished by the hospital and other providers and suppliers throughout the episode to improve the quality and efficiency of care. With these incentives present, there may be a reduced likelihood of over-utilization of services that could otherwise result from waivers of Medicare program rules. Given these circumstances, waivers of certain program rules for providers and suppliers furnishing services to CJR-X beneficiaries may be appropriate to offer more flexibility than under existing Medicare rules for such providers and suppliers, so that they may provide appropriate, efficient care for beneficiaries. An example of such a program rule that could be waived to potentially allow more efficient inpatient episodes would be the 3-day inpatient hospital stay requirement prior to a covered skilled nursing facility (SNF) stay for beneficiaries who could appropriately be discharged to a SNF or swing bed after less than a 3-day inpatient hospital stay. This type of waiver was implemented in a range of previous and existing CMS initiatives, including various episode-based payment models and accountable care initiatives such as the CJR Model and its successor model, TEAM. Keeping these waivers in the expansion of CJR-X will build on past successes.

We welcome comments on possible waivers under section 1115A of the Act of certain Medicare program rules beyond those specifically discussed in this proposed rule that might be necessary to test this model. We will consider the comments that are received during the public comment period and may make future proposals regarding program rule waivers during the course of the model test. We are especially interested in comments explaining how such waivers could provide providers and suppliers with additional flexibilities that are not permitted under existing Medicare rules to increase quality of care and reduce unnecessary episode spending, but that could be appropriately used in the context of CJR-X where CJR-X participants bear

full responsibility for total episode spending.

Specific program rules for which we propose waivers under CJR-X to support provider and supplier efforts to increase quality and decrease episode spending and for which we invite comments are included in the sections that follow. We propose that these waivers of program rules would apply to the care of CJR-X beneficiaries who are in episodes at the time when the waiver is used to bill for a service that is furnished to the beneficiary, even if the episode is later cancelled as described in section X.C.2.d.(3)(e) of this proposed rule. Finally, we propose that if a service is found to have been billed and paid by Medicare under circumstances only allowed by a CJR-X program rule waiver for a beneficiary not in CJR-X at the time the service was furnished, CMS would recover payment for that service from the provider or supplier who was paid, and require that provider and supplier to repay the beneficiary for any coinsurance previously collected.

##### (2) Post-Discharge Home Visits

The CJR Model permitted certain post-discharge home visits during the episode of care to encourage CJR participant hospitals to closely examine the most appropriate PAC settings for beneficiaries, taking into consideration beneficiary choice and location of beneficiary home or place of residence, so that the clinically appropriate setting of the lowest acuity was recommended following discharge from the anchor hospitalization or anchor procedure. Consistent with the CJR Model and CJR-X's goals of improving quality and reducing unnecessary Medicare expenditures, we believe continuing such regulatory flexibilities would support clinically appropriate home-based follow-up care may further advance effective episode management.

Early post-discharge periods represent a time of heightened clinical vulnerability for beneficiaries undergoing joint replacement. Complications such as infection, medication-related issues, and mobility limitations frequently arise within the first weeks following discharge and may result in avoidable emergency department visits, readmissions, or use of institutional post-acute care services. We believe that timely, in-person home visits furnished by qualified clinicians may help identify emerging complications, reinforce discharge instructions, support medication reconciliation, and facilitate adherence to rehabilitation plans in the beneficiary's home environment.

We also anticipate that permitting targeted post-discharge home visits would promote safe discharge to home when clinically appropriate, potentially reducing reliance on higher-cost institutional post-acute care settings. Post-acute care spending represents a significant portion of episode spending, therefore enabling home-based clinical monitoring and care coordination, may support CJR-X participants' efforts to redesign care pathways in ways that improve outcomes while lowering total episode expenditures.

In the BPCI Advanced and CJR Models (80 FR 73444), we provided a waiver of the "incident to" rule to allow a physician or nonphysician practitioner participating in care redesign under a participating provider to bill for services furnished to a beneficiary who does not qualify for Medicare coverage of home health services as set forth under § 409.42 where the services are furnished in the beneficiary's home during the episode after the beneficiary's discharge from an acute care hospital. The "incident to" rules are set forth in § 410.26(b)(5), which requires services and supplies furnished incident to the service of a physician or other practitioner must be provided under the "direct supervision" (as defined at § 410.32(b)(3)(ii)) of a physician or other practitioner.

In the BPCI Advanced and CJR Models, the waiver is available only for services that are furnished by licensed clinical staff under the "general supervision" (as defined at § 410.32(b)(3)(i)) of a physician (or other practitioner), or other qualified health care professional, and who are allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but do not individually report that professional service. While the services may be furnished by licensed clinical staff, they must be billed by the physician (or other practitioner) or participant to which the supervising physician has reassigned their billing rights in accordance with CMS instructions using a Healthcare Common Procedures Coding System (HCPCS) G-code created by CMS specifically for the BPCI Advanced or CJR Models. In the case of the incident to waiver under BPCI Advanced, the waiver allows physician and nonphysician practitioners to furnish the services up to 13 home visits during each 90-day clinical episode. In the case of the incident to waiver under the original CJR Model, the waiver allows physician and nonphysician practitioners to furnish the services up to 9 home visits during each 90-day clinical episode. This waiver was later

modified to apply to anchor procedures in the CJR Extension (86 FR 23552). All other Medicare coverage and payment criteria must be met for both BPCI Advanced and CJR Models.

We recognize TEAM did not waive the "incident to" rule set forth in § 410.26(b)(5) given the low waiver utilization in other CMS models and initiatives. However, we have determined to keep continuity between CJR-X and the CJR Extension to preserve the policies tested as it pertains to model waivers. However, we can monitor utilization and reassess the necessity of this waiver at a later date. We believe this will ensure the integrity of model policies between the CJR Model and CJR-X as it expands nationally. Therefore, we propose to waive the "incident to" rule set forth in § 410.26(b)(5), to allow a CJR-X beneficiary who does not qualify for home health services to receive post-discharge visits in his or her home or place of residence any time during the episode. The waiver would not apply to beneficiaries who would qualify for home health services under the Medicare program, as set forth under § 409.42. Therefore, these visits would not be billed for such beneficiaries. Under the proposed waiver, we would allow licensed clinical staff, such as nurses, either employed by a hospital or not, to furnish the service under the general supervision of a physician, who may be either an employee or a contractor of the hospital. We would allow services furnished under the waiver to be billed under the physician fees schedule by the physician or nonphysician practitioner or by the hospital to which the supervising physician has reassigned his or her benefits. In the latter scenario, we note that the post-discharge home visit services will not be "hospital services," even when furnished by clinical staff of the hospital. We plan to monitor patterns of utilization of home health services using this waiver under CJR-X to monitor for overutilization or reductions in medically necessary care, and significant reductions. By using this waiver now and monitoring use, we can evaluate effectiveness and redetermine its necessity if deemed superfluous.

Under the CJR Model, we allowed up to 9 post-discharge home visits to be billed and paid during each 90-day post-anchor hospitalization or anchor procedure. This limit on the number of visits is based on the average post-acute care LOS of approximately 30 to 45 days for original CJR episodes and the incentives under original CJR to improve efficiency, which may shorten post-acute care stays. Thus, 9 visits

represent a home visit on average of once per week for two-thirds of the 90-day episode duration, the period of time when the typical beneficiary may have concluded post-acute care in an efficient episode. We propose to adopt the same number of post-discharge home visits in CJR-X. Specifically, we propose to allow up to 9 post-discharge home visits to be billed and paid during each 90-day post-anchor hospitalization or anchor procedure. We also propose that the service be billed with a HCPCS code G-code. The G-code would be created before the start of CJR-X and would be specific to CJR-X to allow for a home visit for patient assessment performed by clinical staff for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and ensuring CJR-X beneficiary connections to community and other services; for use only in CJR-X; may not be billed for a 30-day period covered by a transitional care management code. We propose the G-code would be paid at approximately \$50 under the physician fee schedule. The standard physician fee schedule rate setting methodologies establish relative value units (RVUs) based on the resources required to furnish the typical service. In addition, we propose to update the values each year to correspond to final values established under the physician fee schedule.

The waiver would not apply with respect to a CJR-X beneficiary who has qualified, or would qualify, for home health services when the visit was furnished. We expect that the visits by licensed clinical staff could include patient assessment, monitoring, assessment of functional status and fall risk, review of medications, assessment of adherence with treatment recommendations, patient education, communication and coordination with other treating clinicians, care management to improve beneficiary connections to community and other services, etc. These post-discharge home visits would remove barriers to follow-up care outside of the home with providers and suppliers and allow the CJR-X beneficiary to be treated in his or her home environment or place of residence, where potential safety concerns, such as tripping hazards, could quickly be identified and remediated. Given these occasions for further patient assessment and intervention, we believe that where

such post-discharge home visits are furnished, there are opportunities to increase patient-centered care coordination and decrease episode spending, potentially resulting in higher-quality care for beneficiaries and increased episode efficiency which may benefit the beneficiaries, the Medicare Trust Fund, and CJR–X participants.

We also propose to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. The physician fee schedule payment for the surgical procedure includes 90 days of post-operative care furnished by the surgeon. Post-operative follow-up care is not separately billable by the surgeon or, unless there is a transfer of care, by another practitioner. The current construction of the global packages included in physician fee schedule payments reflects a narrow view of surgical follow-up care that does not encompass broader, more comprehensive models of post-operative care, such as an episode payment model CJR–X. We do not believe that the CJR–X post-discharge home visits, which can include nursing assessments for chronic conditions for which care may be affected by the surgery, would replace or substantially duplicate the kind of post-operative visits involved in furnishing post-operative follow-up care for the global surgery procedure under the physician fee schedule. Instead, we anticipate that the work of these post-discharge visits will be similar to the work furnished by the physician coordinating the patient's overall episode care. Therefore, we propose to waive the global surgery billing rules to allow the surgeon or other practitioners to furnish and bill for the post-discharge home visits during surgical global periods.

We seek comments at § 512.695(c) on the proposed waiver of the “incident to” rule to pay for a maximum number of nine post-discharge home visits to beneficiaries who do not qualify for home health services by licensed clinical staff under the general supervision of a physician.

### (3) Telehealth

The CJR Model waived certain telehealth service requirements to allow providers and suppliers furnishing services to model beneficiaries to utilize telemedicine for beneficiaries that are not classified as rural and allowed the greatest degree of efficiency and communication between providers and suppliers and beneficiaries by allowing beneficiaries to receive telehealth services at their home or place of

residence. We believe similar telehealth waivers would be essential to maximize the opportunity to improve the quality of care and efficiency for episodes of care in CJR–X.

Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. The telehealth services must be furnished to a beneficiary located in one of the ten types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act and the site must satisfy at least one of the requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. Generally, for Medicare payment to be made for telehealth services under the Medicare Physician Fee Schedule several conditions must be met, as set forth under § 410.78(b). Specifically, the service must be on the Medicare list of telehealth services and meet all of the following other requirements for payment:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the services must be in an eligible originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. Section 1834(m)(4)(F)(i) of the Act defines “Medicare telehealth services” to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. For the list of approved Medicare telehealth services, see the CMS website at <https://www.cms.gov/medicare/coverage/telehealth/list-services>. Under section 1834(m)(4)(F)(ii) of the Act, CMS has an annual process to consider additions to and deletions from the list of telehealth services. We do not include any services as telehealth services when Medicare does not otherwise make a separate payment for them.

In the CJR Model (80 FR 73274) as well as the national COVID–19 public health emergency (PHE) telehealth waiver,<sup>485</sup> and in the most recent Consolidated Appropriations Act, 2026, hospitals were permitted to use

telehealth waivers that applied to two provisions:

- CMS waived the geographic site requirements under 1834(m)(4)(C)(i)(I) through (III) of the Act which allowed telehealth services to be furnished to eligible telehealth individuals when they are located at one of the eight originating sites at the time the service is furnished via a telecommunications system but without regard to the site meeting one of the geographic site requirements.
- CMS waived the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (X) of the Act which allowed the eligible telehealth individual to not be in an originating site when the otherwise eligible individual is receiving telehealth services in their home or place of residence.

Specifically, like the telehealth waivers in the CJR Model (80 FR 73448), we propose to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Waiver of this requirement would allow beneficiaries located in any region to receive services related to the episode to be furnished via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare approved telehealth services and reported on a claim that is not excluded from the proposed episode definition (see section X.C.2.d.(3). of this proposed rule) could be furnished to a CJR–X beneficiary, regardless of the CJR–X beneficiary's geographic location. Under CJR–X, this waiver would support care coordination and increasing timely access to high quality care for all CJR–X beneficiaries, regardless of geography. Additionally, we propose for CJR–X waiving the originating site requirements of section 1834(m)(4)(C)(ii)(I) through (X) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Specifically, we propose to waive the requirement only when telehealth services are being furnished in the CJR–X beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services that is not excluded from the proposed episode definition (see section X.C.2.d.(3)(b). of this proposed rule) could be furnished to a

<sup>485</sup> Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, P.L. 116–123 § 101 (Mar. 6, 2020) <https://www.govinfo.gov/content/pkg/BILLS-116hr748enr/pdf/BILLS-116hr748enr.pdf>.



CJR–X beneficiary in their home or place of residence, unless the service’s HCPCS code descriptor precludes delivering the service in the home or place of residence. For example, subsequent hospital care services could not be furnished to beneficiaries in their home since those beneficiaries would not be inpatients of the hospital. Though these activities are allowed via broad Medicare telehealth waivers, as recently extended under the Consolidated Appropriations Act, 2026, these waivers are not permanent and has been subject to reconsiderations and extensions by Congress. A CJR–X telehealth waiver would guarantee telehealth services mentioned in this waiver could continue for CJR–X participants even if the broad Medicare telehealth waivers expire.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are located in that setting. Section 1834(m) of the Act provides for particular conditions under which Medicare can make payment for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere.

However, we do not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This would include circumstances when the patient is located in his or her home and the location of the practitioner is unspecified. In order to create a mechanism to report E/M services accurately, the BPCI Advanced and CJR Models (80 FR 73450) created specific sets of HCPCS G-codes to describe the E/M services furnished to the model beneficiaries in their homes via telehealth. Similarly for CJR–X, we propose to create a specific set of 4 HCPCS G-codes to describe the E/M services furnished to CJR–X beneficiaries in their homes via telehealth. If the proposed CJR–X is finalized, we would specify the precise G-code created for CJR–X and share them to CJR–X participants prior to the first performance year.

Among the existing E/M visit services, we envision these services would be most similar to those described by the office and other outpatient E/M codes. Therefore, we propose to structure the new codes similarly to the office/outpatient E/M codes but adjusted to reflect the location as the CJR–X

beneficiary’s residence and the virtual presence of the practitioner. Specifically, we propose to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services, see Table X.C–06, for CPT codes CPT codes 99212 through 99215 for established patient visits. For example, the proposed G-code for a level 3 E/M visit for an established patient would be a telehealth visit for the evaluation and management of an established patient in the patient’s home, which requires at least 2 of the following 3 key components:

- An expanded problem focused history;
- An expanded problem focused examination;
- Medical decision making of low complexity.

Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the patient’s or family’s needs or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent with the patient or family or both via real-time, audio and video intercommunications technology.

**TABLE X.C-06: PROPOSED CJR-X TELEHEALTH WAIVER G-CODE CROSSWALK**

| TEAM G-Code<br>(Used for illustrative purposes. Specific G-codes<br>will be created if TEAM is finalized.) | Short Descriptor          | Corresponding Office/Outpatient E/M<br>CPT Code |
|------------------------------------------------------------------------------------------------------------|---------------------------|-------------------------------------------------|
| GXXX12                                                                                                     | Remote E/M est. pt 10mins | 99212                                           |
| GXXX13                                                                                                     | Remote E/M est. pt 20mins | 99213                                           |
| GXXX14                                                                                                     | Remote E/M est. pt 30mins | 99214                                           |
| GXXX15                                                                                                     | Remote E/M est. pt 40mins | 99215                                           |

We note that we are not proposing a G-code to parallel the level 1 office/outpatient visit for an established patient, since that service does not require the presence of the physician or other qualified health professional.

We propose to develop payment rates for these new telehealth G-codes for E/M services in the patient’s home that are similar to the payment rates for the office/outpatient E/M services, since the codes will describe the work involved in furnishing similar services. Therefore, we propose to include the resource costs typically incurred when services are furnished via telehealth. In terms of the relative resource costs involved in furnishing these services, we believe that the efficiencies of virtual presentation generally limit resource costs other than those related to the professional time, intensity, and

malpractice risk to marginal levels. Therefore, we propose to adopt work and malpractice (MP) RVUs associated with the corresponding level of office/outpatient codes as the typical service because the practitioner’s time and intensity and malpractice liabilities when conducting a visit via telehealth are comparable to the office visit. We would include final RVUs under the CY 2027 Medicare Physician Fee Schedule for PY 1. Additionally, we propose to update these values each performance year to correspond to final values established under the Medicare Physician Fee Schedule.

We considered whether each level of visit typically would warrant support by auxiliary licensed clinical staff within the context of CJR–X. The cost of such staff and any associated supplies, for example, would be incorporated in the

practice expense (PE) RVUs under the PFS. For the lower level visits, levels 2 and 3 for established visits, we did not believe that the visit would necessarily require auxiliary medical staff to be available in the patient’s home. We anticipate these lower level visits would be the most commonly furnished and would serve as a mechanism for the patient to consult quickly with a practitioner for concerns that can be easily described and explained by the patient. We do not propose to include PE RVUs for these services, since we do not believe that virtual visits envisioned for this model typically incur the kinds of costs included in the PE RVUs under the Medicare Physician Fee Schedule. For higher level visits, we typically would anticipate some amount of support from auxiliary clinical staff. For example, wound examination and



minor wound debridement would be considered included in an E/M visit and would require licensed clinical staff to be present in the CJR–X beneficiary's home during the telehealth visit in order for the complete service to be furnished. We believe it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for CJR–X beneficiaries in episodes without licensed clinical staff support in the home.

We have considered support by auxiliary clinical staff to be typical for level 4 or 5 E/M visits furnished to CJR–X beneficiaries in the home via telehealth, however, we do not propose to incorporate these costs through PE RVUs. Given the anticipated complexity of these visits, we would expect to observe level 4 and 5 E/M visits to be reported on the same claim with the same date of service as a home visit or during a period of authorized home health care. If neither of these occurs, we propose to require the physician to document in the medical record that auxiliary licensed clinical staff were available on site in the patient's home during the visit and if they were not, to document the reason that such a high-level visit would not require such personnel.

We note that because the services described by the proposed G-codes, by definition, are furnished remotely using telecommunications technology, they therefore are paid under the same conditions as in-person physicians' services and they do not require a waiver to the requirements of section 1834(m) of the Act. We also note that because these home telehealth services are E/M services, all other coverage and payment rules regarding E/M services would continue to apply.

Under CJR–X, this proposal to waive the originating site requirements and create new home visit telehealth HCPCS codes would support the greatest efficiency and timely communication between providers and beneficiaries by allowing beneficiaries to receive telehealth services at their places of residence.

With respect to home health services paid under the home health prospective payment system (HH PPS), we emphasize that telehealth visits under this model cannot substitute for in-person home health visits per section 1895(e)(1)(A) of the Act. Furthermore, telehealth services by social workers cannot be furnished for CJR–X beneficiaries who are in a home health episode because medical social services are included as home health services per section 1861(m) of the Act and paid

for under the Medicare HH PPS. However, telehealth services permitted under section 1834 of the Act and furnished by physicians or other practitioners, specifically physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, nurse anesthetists, psychologists, and dietitians, can be furnished for CJR–X beneficiaries who are in a home health episode. Finally, sections 1835(a) and 1814(a) of the Act require that the patient has a face-to-face encounter with the certifying physician or an allowed nonphysician practitioner (NPP) working in collaboration with or under the supervision of the certifying physician before the certifying physician certifies that the patient is eligible for home health services. Under § 424.22(a)(1)(v), the face-to-face encounter can be performed up to 90 days prior to the start of home health care or within 30 days after the start of home health care. Section § 424.22(a)(1)(v)(A) also allows a physician, with privileges, who cared for the patient in an acute or PAC setting (from which the patient was directly admitted to home health) or an allowed NPP working in collaboration with or under the supervision of the acute or PAC physician to conduct the face-to-face encounter.

Although sections 1835(a) and 1814(a) of the Act allow the face-to-face encounter to be performed via telehealth, we are not proposing that the waiver of the telehealth geographic site requirement for telehealth services and the originating site requirement for telehealth services furnished in the CJR–X beneficiary's home or place of residence would apply to the face-to-face encounter required as part of the home health certification when that encounter is furnished via telehealth. In other words, when a face-to-face encounter furnished via telehealth is used to meet the requirement for home health certification, the usual Medicare telehealth rules apply with respect to geography and eligibility of the originating site. We expect that this policy would not limit CJR–X beneficiaries' access to medically necessary home health services because beneficiaries receiving home health services during an episode will have had a face-to-face encounter with either the physician or an allowed NPP during their anchor hospitalization or a physician or allowed NPP during a post-acute facility stay prior to discharge directly to home health services.

Under the proposed waiver of the geographic site requirement and originating site requirement, all telehealth services would be required to

be furnished in accordance with all Medicare coverage and payment criteria, and no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service would be waived if there is no facility as an originating site (that is, the service was originated in the CJR–X beneficiary's home). Finally, providers and suppliers furnishing a telehealth service to a CJR–X beneficiary in his or her home or place of residence during the episode would not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service. CJR–X beneficiaries would be able to receive services furnished pursuant to the telehealth waivers only during the episode.

We plan to monitor patterns of utilization of telehealth services under CJR–X to monitor for overutilization or reductions in medically necessary care, and significant reductions in face-to-face visits with physicians and NPPs. Though this waiver existed in the CJR Model, the broader Medicare telehealth waivers also covered much of the CJR Model. By including a telehealth waiver specific to CJR–X now and monitoring use, we could gauge effectiveness and guarantee its access even if the broad Medicare telehealth waiver, that were recently extended under the Consolidated Appropriations Act, 2026, expires. We plan to specifically monitor the distribution of new telehealth home visits that we are proposing, as we anticipate greater use of lower level visits. Given our concern that auxiliary licensed clinical staff be present for level 4 and 5 visits, we will monitor our proposed requirement that these visits be billed on the same claim with the same date of service as a home nursing visit, during a period authorized home health care, or that the physician document the presence of auxiliary licensed clinical staff in the home or an explanation as to the specific circumstances precluding the need for auxiliary staff for the specific visit.

We seek comment on the proposed waivers with respect to telehealth services and the proposed creation of the home visit telehealth codes at § 512.695(a).

#### (4) 3-Day SNF Rule

Pursuant to section 1861(i) of the Act, a beneficiary must have a prior inpatient hospital stays of no fewer than 3 consecutive days to be eligible for

Medicare coverage of inpatient SNF care. We refer to this as the SNF 3-day rule. We note that the SNF 3-day rule has been waived for Medicare SNF coverage under many Innovation Center initiatives, including other episode payment models such as the BPCI Advanced and CJR Models (80 FR 73460), as well as the Medicare Shared Savings Program. Model and program participants that elect to use the waiver can discharge model beneficiaries in fewer than 3 days from an anchor hospital stay or anchor procedure (in the case of the CJR Model) to a SNF, or swing bed, where services are covered under Medicare Part A if all other coverage requirements for such services are satisfied.

Because of the potential benefits we see for CJR-X participants, their provider partners, and beneficiaries, we propose to waive the SNF 3-day rule for coverage of a SNF stay following the anchor hospitalization or anchor procedure under CJR-X. We propose to use our authority under section 1115A of the Act with respect to certain SNFs that furnish Medicare Part A post-hospital extended care services to beneficiaries included in an episode in CJR-X. We believe this waiver is necessary to the model test so that CJR-X participants can redesign care throughout the episode continuum of care extending to 90 days post-discharge from the anchor hospital stay or anchor procedure to maximize quality and hospital financial efficiency, as well as reduce episode spending under Medicare. All other Medicare rules for coverage and payment of Part A-covered SNF services would continue to apply to CJR-X beneficiaries in all performance years of the model. Further, to ensure protection to CJR-X beneficiary safety and optimize health outcomes, we propose to require that CJR-X participants may only discharge a CJR-X beneficiary under this proposed waiver of the SNF 3-day rule to a SNF rated an overall of three stars or better by CMS based on information publicly available at the time of hospital discharge from an anchor hospital stay or anchor procedure. However, providers furnishing SNF services under swing bed agreements will not be subject to the star ratings requirement as described later in this section. Problem areas due to early hospital discharge may not be discovered through model monitoring and evaluation activities until well after the episode has concluded, and the potential for later negative findings alone may not afford sufficient CJR-X beneficiary protections. CMS created a Five-Star Quality Rating

System for SNFs to allow SNFs to be compared more easily and to help identify areas of concerning SNF performance. The Nursing Home Compare website gives each SNF an overall rating of between 1 and 5 stars.<sup>486</sup> Those SNFs with 5 stars are considered to have much above average quality, and SNFs with 1 star are considered to have quality much below average. Published SNF ratings include distinct ratings of health inspection, staffing, and quality measures, with ratings for each of the three sources combined to calculate an overall rating. These areas of assessment are all relevant to the quality of SNF care following discharge from the anchor hospitalization or anchor procedure initiating an episode, especially if that discharge occurs after fewer than 3 days in the hospital. Because of the potential greater risks following early inpatient hospital discharge, we believe it is appropriate that all CJR-X beneficiaries discharged from the CJR-X participant to a SNF, or swing bed, in fewer than 3 days be admitted to a SNF that has demonstrated that it can provide quality care to patients with significant unresolved post-surgical symptoms and problems. We believe such a SNF would need to provide care of at least average overall quality, which would be represented by an overall SNF 3-star or better rating.

Thus, the CJR-X participant must discharge the CJR-X beneficiary to a SNF that is qualified under the SNF 3-day rule waiver. We are proposing that to be qualified under the SNF 3-day rule waiver a SNF must be included in the most recent calendar year quarter Five-Star Quality Rating System listing for SNFs on the Nursing Home Compare website for the date of the CJR-X beneficiary's admission to the SNF. The qualified SNF must be rated an overall 3 stars or better for at least 7 of the 12 months based on a review of the most recent rolling 12 months of overall star ratings, unless providers furnishing SNF services are doing so under swing bed agreements. We propose to post on the CMS website the list of qualified SNFs in advance of the calendar quarter.

We recognize that there may be instances where a CJR-X participant would like to use the 3-day SNF rule waiver, but the CJR-X beneficiary receives inpatient PAC through swing bed arrangements in a hospital or Critical Access Hospital (CAH), as designated in § 485.606 of this chapter,

which is not subject to the Five-Star Quality Rating System. For example, a CJR-X beneficiary located in a rural area may wish to receive PAC care closer to their home but there are no qualified SNFs in their area. The CJR Model (80 FR 73459) did not allow for exceptions to the star-rating requirements in the 3-day SNF waiver out of a concern for balancing the needs of participant flexibilities and beneficiary protections. However, in TEAM we finalized a policy allowing hospitals with swing beds arrangements to make use of the 3-day SNF waiver (90 FR 37130). Similar to TEAM, we propose allowing CJR-X participants to use the 3-day SNF rule waiver for hospitals and CAHs operating under swing bed agreements to support CJR-X beneficiary freedom of choice and provide greater flexibility to CJR-X participants for their care coordination efforts. We also propose for purposes of determining SNF qualification for the SNF 3-day rule waiver, that SNFs include providers furnishing SNF services under swing bed arrangements. Lastly, we propose that the minimum 3-star rating requirement for at least 7 of the past 12 months applies only if the provider furnishing SNF services is eligible to be included in the CMS Five-Star Quality Rating System. This approach is also consistent with the Shared Savings Program, which offers a similar 3-day SNF rule waiver and allows their ACOs to partner with hospitals and CAHs to with swing bed arrangements to utilize the waiver.

We plan to monitor patterns of SNF utilization under the CJR-X, particularly with respect to hospital discharge in fewer than 3 days to a SNF, to ensure that CJR-X beneficiaries are not being discharged prematurely to SNFs and that they are able to exercise their freedom of choice without patient steering.

We seek comment on our proposal at § 512.695(b)(1) through (4) to waive the SNF 3-day stay rule following discharge from the anchor hospitalization or anchor procedures for episodes in CJR-X.

#### (a) Additional Beneficiary Protections Under the SNF 3-Day Stay Rule Waiver

We believe that it will be necessary to propose beneficiary protections against financial liability in addition to the beneficiary protections discussed elsewhere in this proposed rule. Specifically, we believe it is important to discern whether a waiver applies to SNF services furnished to a particular beneficiary to ensure compliance with the conditions of the waiver and improve our ability to monitor waivers for misuse.

<sup>486</sup> Find & Compare Providers near you. Medicare.gov. <https://www.medicare.gov/care-compare/?redirect=true&providerType=NursingHome>.

In considering additional beneficiary protections that may be necessary to ensure proper use of SNF 3-day rule waiver under the CJR-X, we note that there are existing, well-established payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act that include protections for beneficiaries from liability for certain non-covered SNF charges. These existing payment and coverage policies for SNF services continue to apply under the CJR-X, including SNF services furnished pursuant to the SNF 3-day waiver. (For example, see section 70 in the Medicare Claims Processing Manual, Chapter 30—Financial Liability Protections on the CMS website at <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c30.pdf>; and Medicare Coverage of Skilled Nursing Facility Care <https://www.medicare.gov/coverage/skilled-nursing-facility-snf-care>; Medicare Benefit Policy Manual, Chapter 8—Coverage of Extended Care (SNF) Services Under Hospital Insurance at <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c08pdf.pdf>). In general, CMS requires that the SNF inform a beneficiary in writing about services and fees before the beneficiary is discharged to the SNF (§ 483.10(b)(6)); the beneficiary cannot be charged by the SNF for items or services that were not requested (§ 483.10(c)(8)(iii)(A)); a beneficiary cannot be required to request extra services as a condition of continued stay (§ 483.10(c)(8)(iii)(B)); and the SNF must inform a beneficiary that requests an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be (§ 483.10(c)(8)(iii)(C)). (See also section 6 of Medicare Coverage of Skilled Nursing Facility Care at <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c06.pdf>.)

As we discussed in the 2015 CJR final rule (80 FR 73454 through 73460), commenters expressed concern regarding the lag between a CJR beneficiary's Medicare coverage or eligibility status change and a CJR-X participant's awareness of that change. There may be cases in which a SNF waiver is used by a CJR-X participant because the CJR-X participant believes that the beneficiary meets the inclusion criteria, based on the information available to the hospital and SNF at the time of the beneficiary's admission to the SNF, but in fact the beneficiary's Medicare coverage has changed and the

hospital was unaware of it based on available information. We recognize that despite good faith efforts by CJR-X participants and SNFs to determine a beneficiary's Medicare status for the model, it may occur that a beneficiary is not eligible to be included in the CJR-X at the time the SNF waiver is used. In these cases, we will cover services furnished under the waiver when the information available to the provider at the time the services under the waiver were furnished indicated that the beneficiary was included in the model.

Based on our experience with SNF 3-day rule waiver, including in the CJR Model, we believe there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day waiver for the CJR-X. Specifically, we are concerned about potential beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day waiver under the CJR-X. We are concerned that there could be scenarios where a CJR-X beneficiary could be charged for non-covered SNF services that were a result of a CJR-X participant's inappropriate use of the SNF waiver. Specifically, we are concerned that a CJR-X beneficiary could be charged for non-covered SNF services if a CJR-X participant discharges a CJR-X beneficiary to a SNF that does not meet the quality requirement (3 stars or higher in 7 of the last 12 months), and payment for SNF services is denied for lack of a qualifying inpatient hospital stay. We recognize that requiring a discharge planning notice would help mitigate concerns about CJR-X beneficiaries' potential financial liability for non-covered services. Nevertheless, we are concerned that in this scenario, once the claim is rejected, the CJR-X beneficiary may not be protected from financial liability under existing Medicare rules because the waiver would not be available, and the CJR-X beneficiary would not have had a qualifying inpatient hospital stay. Thus, the CJR-X beneficiary could be charged by the SNF for non-covered SNF services that were a result of an inappropriate attempt to use the waiver. In this scenario, Medicare would deny payment of the SNF claim, and the CJR-X beneficiary could potentially be charged by the SNF for these non-covered SNF services, potentially subjecting such CJR-X beneficiaries to significant financial liability. In this circumstance, we assume the CJR-X participant's intent was to rely upon the SNF 3-day waiver, but the waiver requirements were not met. We believe

that in this scenario, the rejection of the claim could easily have been avoided if the hospital had confirmed that the requirements for use of the SNF 3-day waiver were satisfied or if the CJR-X beneficiary had been provided the discharge planning notice and elected to go to a SNF that met the quality requirement.

The CJR Model modifications in the 2016 EPM rule (82 FR 180) addressed beneficiary liability financial concerns for non-covered SNF services related to the waiver by generally placing the risk on the participant hospital and we believe it is appropriate to propose a similar policy for CJR-X. Original CJR participant hospitals were generally held financially responsible for misusing the waiver in situations where waiver requirements are not met, because participant hospitals were required to be aware of the 3-day waiver requirements. Participant hospitals were the entities financially responsible for episode spending under the model and made the decision as to whether it is appropriate to discharge a beneficiary without a 3-day stay. In addition, the requirements for use of the SNF waiver were clearly laid out in the 2015 CJR Final Rule (80 FR 73460). CMS posted on the public website a list of qualifying SNFs (those with a 3-star or higher rating for 7 of the last 12 months). Original CJR participant hospitals were required to consult the published list of SNFs prior to utilizing the SNF 3-day rule waiver.

For participant hospitals that provide a beneficiary with the discharge planning notice, the hospital would not have financial liability for non-covered SNF services that result from inapplicability of the waiver. In other words, when the participant hospital has discharged a beneficiary to a SNF that does not qualify under the conditions of the waiver, and has not provided the required discharge planning notice so that the beneficiary is aware that he or she is accepting financial liability for non-covered SNF services as a result of not having a qualifying inpatient stay, the ultimate responsibility and financial liability for the non-covered SNF stay rests with the participant hospital. For this reason, we are proposing to align with the CJR Model policy and require CJR-X participants to keep a record of discharge planning notice distribution to CJR-X beneficiaries. We will monitor CJR-X participants' use of discharge planning notices to assess the potential for their misuse.

To protect CJR-X beneficiaries from being charged for non-covered SNF charges in instances when the waiver

was used inappropriately, and similar to the CJR Model (82 FR 558), we are proposing to add certain beneficiary protection requirements that would apply for SNF services that would otherwise have been covered except for lack of a qualifying hospital stay. Specifically, we propose that if a CJR–X participant discharges a CJR–X beneficiary without a qualifying 3-day inpatient stay to a SNF that is not on the published list of SNFs that meet the CJR–X SNF 3-Day Rule waiver quality requirements as of the date of admission to the SNF, the CJR–X participant will be financially liable for the SNF stay if no discharge planning notice is provided to the CJR–X beneficiary, alerting them of potential financial liability. If the CJR–X participant provides a discharge planning notice then the CJR–X participant will not be financially liable for the cost of the SNF stay and the normal Medicare FFS rules for coverage of SNF services will apply. In cases where the CJR–X participant provides a discharge planning notice and the CJR–X beneficiary chooses to obtain care from a non-qualified SNF without a qualifying inpatient stay, the CJR–X beneficiary assumes financial liability for services furnished (except those that are covered by Medicare Part B during a non-covered inpatient SNF stay).

In the event a CJR–X beneficiary is discharged to a SNF without a qualifying 3-day inpatient stay, but the SNF is not on the qualified list as of the date of admission to the SNF, and the CJR–X participant has failed to provide a discharge planning notice, we propose that CMS apply the following rules:

- CMS does not make payment to the SNF for such services.
- The SNF must not charge the CJR–X beneficiary for the expenses incurred for such services; and the SNF must return to the CJR–X beneficiary any monies collected for such services.
- The hospital must be responsible for the cost of the uncovered SNF stay.

We seek comment on these proposals at § 512.695(b)(5) to hold the CJR–X participant financially responsible when the waiver of the SNF 3-day rule is used inappropriately.

#### k. Data Sharing

##### (1) Overview

In this proposed rule, we aim to incentivize CJR–X participants to engage in care redesign efforts to improve quality of care and reduce Medicare FFS spending for beneficiaries included in the model during the anchor hospitalization or anchor procedure and the 90 days post-discharge from the

hospital or hospital outpatient department. These care redesign efforts would require CJR–X participants to work with and coordinate care with other health care providers and suppliers to improve the quality and efficiency of care for Medicare beneficiaries.

We have experience with a range of efforts designed to improve care coordination for Medicare beneficiaries, including the BPCI Advanced and CJR Models (80 FR 73274), both of which make certain Medicare data available to participants to better enable them to achieve their goals. For example, both the BPCI Advanced and CJR Model (80 FR 73515) participants may request to receive beneficiary-identifiable claims data and financial performance data from the baseline period and throughout their tenure in the model to help them better understand the FFS beneficiaries that are receiving services from their providers and help them improve quality of care and conduct care coordination and other care redesign activities to improve patient outcomes or reduce health care for beneficiaries that could have initiated an episode in the model.

Based on our experience with these efforts, as set forth later in this section, we propose to make certain beneficiary-identifiable claims data and regional aggregate data available to participants in CJR–X regarding Medicare FFS beneficiaries who may initiate an episode and be attributed to them in the model. However, we also expect that CJR–X participants are able to, or will work toward, independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services.

##### (2) Beneficiary-Identifiable Claims Data

###### (a) Legal Authority To Share Beneficiary-Identifiable Data

We believe that CJR–X participants may need access to certain Medicare beneficiary-identifiable data for the purposes of evaluating their performance, conducting quality assessment and improvement activities, conducting population-based activities relating to improving health or reducing health care costs, or conducting other health care operations listed in the first or second paragraph of the definition of “health care operations” under the HIPAA Privacy Rule, 45 CFR 164.501. We recognize that there are issues and

sensitivities surrounding the disclosure of beneficiary-identifiable health information, and that several laws place constraints on sharing individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits the disclosure. Here, the HIPAA Privacy Rule would allow for the proposed disclosure of beneficiary-identifiable health information by CMS because it permits the use and disclosure of such data to carry out treatment, payment, and health care operations, as discussed under 45 CFR 164.506. In this proposed rule, we propose to make CJR–X participants accountable for quality and cost outcomes for CJR–X beneficiaries during an anchor hospitalization or anchor procedure and during the 30-day post-discharge period. We believe that it is necessary for the purposes of this model to offer CJR–X participants the ability to request and receive summary or raw beneficiary-identifiable claims data for a 3-year baseline period as well as on a monthly basis during the performance year to help CJR–X participants engage in care coordination and quality improvement activities for CJR–X beneficiaries in an episode. For the 3-year baseline period, CJR–X participants would only receive beneficiary-identifiable claims data for beneficiaries that initiated an episode in their hospital or hospital outpatient department in the 3-year baseline period, and the beneficiary-identifiable claims data shared with the CJR–X participant would be limited to the items and services included in the episode. In other words, the CJR–X participant would not receive beneficiary-identifiable claims data for beneficiaries that were admitted to their hospital or hospital outpatient department and did not initiate an episode in the baseline period. Nor would the CJR–X participant receive beneficiary-identifiable claims data, for beneficiaries who did initiate an episode in their hospital or hospital outpatient department during the baseline period, for items and services that are not included in an episode, such as a primary care visit five days before the episode or a hospital readmission one day after the episode ends. We propose applying a similar approach for the beneficiary-identifiable claims data sharing during the performance year. We believe that these data would constitute the minimum information necessary to enable the CJR–X participant to understand

spending patterns during the episode, appropriately coordinate care, and target care strategies toward individual beneficiaries furnished care by the CJR–X participant and other providers and suppliers.

Under the HIPAA Privacy Rule, covered entities (means a health plan, a health care clearinghouse, and a health care provider who transmits any health information in electronic form in connection with a transaction covered in 45 CFR Subtitle A, Subchapter C) are barred from using or disclosing individually identifiable health information that is “protected health information” or PHI in a manner that is not permitted or required under the HIPAA Privacy Rule, without the individual’s authorization. The Medicare FFS program, a “health plan” function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI. Hospitals, which would be CJR–X participants, are also covered entities, provided they are “health care providers” as defined by 45 CFR 160.103, such as for claims transactions. Since CJR–X participants are hospitals who are covered entities and are the only entity able to request the beneficiary-identifiable data and with whom CMS would share the beneficiary-identifiable data, we believe that the proposed disclosure of the beneficiary claims data for an anchor hospitalization or an anchor procedure plus 30-day post-discharge for episodes included under the CJR–X model would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for “health care operations” purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient’s health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a “health care operations” function that falls within the first two paragraphs of the definition of “health care operations” in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes “conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines” and “population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination” (45 CFR 164.501).

Under our proposal, CJR–X participants would be using the data on their patients to evaluate the

performance of the CJR–X participant and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as “health care operations” under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, as previously discussed, we believe that this provision is extensive enough to cover the uses we would expect a CJR–X participant to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities, specifically hospitals that are CJR–X participants that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of “health care operations.”

When using or disclosing PHI, or when requesting this information from another covered entity, covered entities must make “reasonable efforts to limit” the information that is used, disclosed, or requested to a “minimum necessary” to accomplish the intended purpose of the use, disclosure, or request (45 CFR 164.502(b)). We believe that the provision of the proposed data elements, as described in section X.C.2.k.(2)(c) of this proposed rule, would constitute the minimum data necessary to accomplish the CJR–X’s model goals of the CJR–X participant.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when the federal government maintains a system of records by which information about individuals is retrieved by use of the individual’s personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

“Routine uses” are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records

describing to whom the disclosure will be made and the purpose for the disclosure. For the proposed CJR–X, the system of records would be covered in Master Demonstration, Evaluation, and Research Studies (DERS) for the Office of Research, Development and Information (ORDI) system of record (72 FR 19705). We believe that the proposed data disclosures are consistent with the purpose for which the data discussed in the proposed rule was collected and may be disclosed in accordance with the routine uses applicable to those records.

We note that, as was the case with the CJR Model, in this proposed rule, we propose to disclose beneficiary-identifiable data to only the hospitals that are bearing risk for episodes and not with their collaborators. As stated in the 2015 CJR final rule (80 FR 73515), we believed that the hospitals that are specifically held financially responsible for an episode should make the determination as to which data are needed to manage care and care processes with their collaborators as well as which data they might want to re-disclose, if any, to their collaborators provided they are in compliance with the HIPAA Privacy Rule.

We believe our data sharing proposals are permitted by and are consistent with the authorities and protections available under the aforementioned statutes and regulations. We seek comments on our proposals regarding the authority to share beneficiary-identifiable data with CJR–X participants.

#### (b) Summary and Raw Beneficiary-Identifiable Claims Data Reports

Based on our experience with BPCI Advanced and CJR Model participants, we recognize that TEAM participants could vary with respect to the kinds of beneficiary-identifiable claims information that would best meet their needs. For example, while many CJR–X participants might have the ability to analyze raw claims data, other CJR–X participants could find it more useful to have a summary of these data. Given this, we propose to make beneficiary-identifiable claims data for episodes in CJR–X available through two formats, summary and raw, both for the baseline period and on an ongoing monthly basis during their participation in the model as we do for BPCI Advanced and the CJR Model (80 FR 73308). Summary beneficiary-identifiable claims data summarizes the claims data by combining and categorizing claims data to provide a broad view of the CJR–X participant’s health care expenditures and utilization. For example, a CJR–X participant may use summary beneficiary-identifiable data to identify

total episode spending across all of a CJR-X participant's episodes in a given performance year. Raw beneficiary-identifiable claims data is unrefined and has not been grouped or combined and includes the specific claims fields, as described in the minimum necessary data section X.C.2.k.(2)(c). of this proposed rule, at the episode level. For example, a CJR-X participant may use raw beneficiary-identifiable data to look at a particular episode to identify the diagnosis code(s) that were associated with a hospital readmission for a CJR-X beneficiary.

First, for CJR-X participants who wish to receive summary Medicare Parts A and B claims data, we propose offering CJR-X participants that enter into a CJR-X data sharing agreement with CMS, as specified in section X.C.2.k.(6). of this proposed rule, the option to submit a formal data request for summary beneficiary-identifiable claims data that have been aggregated to provide summary-level spending and utilization data on CJR-X beneficiaries who would be in an episode during the baseline period and performance years in accordance with applicable privacy and security laws and established privacy and security protections. Such summary beneficiary-identifiable claims data would provide tools to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. For example, if the data provided by CMS to a particular CJR-X participant reflects that, relative to their peers, a certain provider is associated with significantly higher rates of inpatient readmissions than the rates experienced by other beneficiaries with similar care needs, that may be evidence that the CJR-X participant could consider, among other things, the appropriateness of that provider, whether other alternatives might be more appropriate, and whether there exist certain care interventions that could be incorporated post-discharge to lower readmission rates.

Secondly, for CJR-X participants who wish to receive raw Medicare Parts A and B claims data, we propose to offer CJR-X participants that enter into a CJR-X data sharing agreement with CMS the opportunity to submit a formal data request for raw beneficiary-identifiable claims data for CJR-X beneficiaries who would be in an episode during the baseline period and performance years in accordance with applicable privacy and security laws and established privacy and security protections. These raw beneficiary-identifiable claims data would be much

more detailed compared to the summary beneficiary-identifiable claims data and include all beneficiary-identifiable claims for all episodes in CJR-X. In addition, they would include episode summaries, indicators for excluded episodes, diagnosis and procedure codes, and enrollment and dual eligibility information for beneficiaries that initiate episodes in CJR-X. Through analysis, these raw beneficiary-identifiable claims data would provide CJR-X participants with information to improve their ability to coordinate and target care strategies as well as to monitor, understand, and manage utilization and expenditure patterns. Such data would also aid them in developing, targeting, and implementing quality improvement programs and initiatives.

The summary and raw beneficiary-identifiable data would allow CJR-X participants to assess summary and raw data on their relevant CJR-X beneficiary population, giving them the flexibility to utilize the data based on their analytic capacity. Therefore, for both the baseline period and as frequently as a monthly basis during an CJR-X participant's performance year, we propose to provide CJR-X participants with an opportunity to request summary beneficiary-identifiable claims data and raw beneficiary-identifiable claims data that would meet minimum necessary requirements in 45 CFR 164.502(b) and 164.514(d) and include Medicare Parts A and B beneficiary-identifiable claims data for CJR-X beneficiaries in an episode during the 3-year baseline period and performance year. This means the summary and raw beneficiary-identifiable claims data would encompass the total expenditures and claims for the proposed episodes, including the anchor hospitalization or anchor procedure, and all non-excluded items and services in an episode covered under Medicare Parts A and B within the 30 days after discharge, including hospital care, post-acute care, and physician services for the CJR-X participant's beneficiaries.

We propose that if a CJR-X participant wishes to receive beneficiary-identifiable claims data, they must submit a formal request for data on an annual basis in a manner form and by a date specified by CMS, indicating if they want summary beneficiary-identifiable data, raw beneficiary-identifiable data, or both, and sign a CJR-X data sharing agreement. To comply with applicable laws and safeguards, we propose the CJR-X participant must attest that—

- The CJR-X participant is requesting claims data of CJR-X beneficiaries who

would be in an episode during the baseline period or performance year as a HIPAA covered entity;

- The CJR-X participant's request reflects the minimum data necessary for the CJR-X participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501; and

- The CJR-X participant's use of claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care and conducting population-based activities relating to improving health or reducing health care costs that are applied uniformly to all CJR-X beneficiaries, in an episode during the baseline period or performance year, and that these data will not be used to reduce, limit or restrict care for specific Medicare beneficiaries.

We propose that the summary and raw beneficiary-identifiable data would be packaged and sent to a data portal (to which the CJR-X participants must request and be granted access) in a "flat" or binary format for the CJR-X participant to retrieve. We also note that, for both the summary and raw beneficiary-identifiable claims data, we would exclude information that is subject to the regulations governing the confidentiality of substance use disorder patient records (42 CFR part 2) from the data shared with a CJR-X participant. We believe our proposal to make data available to CJR-X participants, through the most appropriate means, may be useful to CJR-X participants to determine appropriate ways to increase the coordination of care, improve quality, enhance efficiencies in the delivery system, and otherwise achieve the goals of the proposed model. CJR-X beneficiaries would be informed of CJR-X and the potential sharing of Medicare beneficiary-identifiable claims data through the beneficiary notification, as discussed in section X.C.2.c.(1). of this proposed rule. Further, CMS would make beneficiary-identifiable claims data available to a CJR-X participant for beneficiaries who may be included in episodes, in accordance with applicable privacy and security laws and only in response to the CJR-X participant's request for such data, through the use of an executed CJR-X data sharing agreement with CMS.

We request comments on this proposal to share beneficiary-identifiable claims data with CJR-X participants at § 512.665(b).

## (c) Minimum Necessary Data

We propose CJR–X participants must limit their beneficiary-identifiable data requests, for CJR–X beneficiaries who are in an episode during the baseline period or performance year, to the minimum necessary to accomplish a permitted use of the data. We propose the minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

- Medicare beneficiary identifier (ID).
- Procedure code.
- Sex.
- Diagnosis code.
- Claim ID.
- The from and through dates of service.
- The provider or supplier ID.
- The claim payment type.
- Date of birth and death, if applicable.
- Tax identification number.
- National provider identifier.

We seek comment on the minimum data necessary beneficiary-identifiable information for CJR–X participants to request beneficiary-identifiable information for purposes of conducting permissible health care operations purposes under this model at § 512.665(c).

## (3) Regional Aggregate Data

As discussed in section X.C.2.f.(3). of this proposed rule, we propose to incorporate regional pricing data when establishing target prices for CJR–X participants, similar to the CJR Model's target prices that are constructed at the regional level. As indicated in the 2015 CJR Final Rule (80 FR 73510), we finalized our proposal to share regional pricing data with original CJR participants because it was a factor affecting target prices. Given some of the similar features between the CJR Model and CJR–X proposed in this proposed rule, particularly our proposal to incorporate regional pricing data when establishing target prices under the model, we propose to provide regional aggregate expenditure data available for all Parts A and B claims associated with episodes in CJR–X for the U.S. Census Division in which the CJR–X participant is located, as we similarly provide to hospitals participating in the CJR Model. Specifically, we propose to provide CJR–X participants with regional aggregate data on the total expenditures during an anchor hospitalization or anchor procedure and the 90-day post-discharge period for all Medicare FFS beneficiaries who would have initiated an episode under our proposed episode definitions in section X.C.2.d. of this proposed rule during the

baseline period and performance years. This data would be provided at the regional level; that is, we propose to share regional aggregate data with a CJR–X participant for episodes initiated in the U.S. Census Division where the CJR–X participant is located. These regional aggregate data would be in a format similar to the proposed summary beneficiary-identifiable claims data and would provide summary information on the average episode spending for episodes in CJR–X in the U.S. Census Division in which the CJR–X participant is located. However, the regional aggregate data would not be beneficiary-identifiable and would be de-identified in accordance with HIPAA Privacy Rule, 45 CFR 164.514(b). Further, the regional aggregate data would also comply with CMS data sharing requirements, including the CMS cell suppression policy which stipulates that no cell (for example, admissions, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly. Given the regional aggregate data is de-identified, we propose CJR–X participants would not have to submit a request to receive this data and the data would not be subject to the terms and conditions of the CJR–X data sharing agreement.

We seek comments on our proposal at § 512.665(d) to provide these data to CJR–X participants.

## (4) Timing and Period of Baseline Period Data

We recognize that providing the ability for CJR–X participants to request the summary and raw beneficiary-identifiable claims baseline data and receive regional aggregate baseline data would be important for CJR–X participants to be able to detect unnecessary episode spending, coordinate care, and identify areas for practice transformation, and that early provision of this data, specifically before the “model start date,” as defined in § 512.605, could facilitate their efforts to do so. Also, as discussed in section X.C.2.f.(3)(a). of this proposed rule, target prices would be calculated using a CJR–X participant's historical episode spending during their baseline period. Further, we believe that CJR–X participants would view the episode payment model effort as one involving continuous improvement. As a result, changes initially contemplated by a CJR–X participant could be subsequently revised based on updated information and experiences.

Therefore, as with the BPCI Advanced and CJR Models (80 FR 73511), we propose to make 3-years of baseline period data available to CJR–X

participants, who enter into a CJR–X data sharing agreement with CMS, for beneficiaries who would have been included in an episode had the model been implemented during the baseline period, and intend to make these data available upon request prior to the start of each performance year and in accordance with applicable privacy and security laws and established privacy and security protections. We would provide the 3 years of baseline period data for the summary and raw beneficiary-identifiable data and for the regional aggregate data. We believe that 3 years of baseline period data is sufficient to support a CJR–X participant's ability to detect unnecessary episode spending, coordinate care, and identify areas for practice transformation. We believe that if a CJR–X participant has access to baseline period data for the 3-year period for each performance year used to set target prices, then it would be better able to assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality. We considered proposing to make available 4 years of baseline period data, or offering 1 year of baseline period data, but we believe offering 4 years of baseline period data would not be necessary since target prices in CJR–X are constructed from a 3-year baseline period and 1 year of data may not sufficiently help CJR–X participants identify areas to improve beneficiary health and care coordination or reducing health costs.

Therefore, we propose that the 3-year period utilized for the baseline period match the baseline data used to create CJR–X participants target prices every performance year, and roll forward one year every performance year, as discussed in section X.C.2.f.(3)(a) of this proposed rule. Specifically, we propose that the baseline period data for the summary and raw beneficiary-identifiable data reports and regional aggregate data report would be shared annually at least 1 month prior to the start of a performance year and available for episodes initiated in the baseline period, as discussed in section X.C.2.f.(3)(a). in this proposed rule.

We request comments on these proposals at proposed § 512.665(b)(6)(i) and (d)(1)(i) to share beneficiary-identifiable data and regional aggregate data for a 3-year baseline period at least 1 month prior to the start of a performance year.

## (5) Timing and Period of Performance Year Data

The availability of periodically updated raw and summary beneficiary-



identifiable claims data and regional aggregate data would assist CJR–X participants to identify areas where they might wish to change their care practice patterns, as well as monitor the effects of any such changes. With respect to these purposes, we have considered what would be the most appropriate period for making updated raw and summary beneficiary-identifiable claims data and regional aggregate data available to CJR–X participants, while complying with the HIPAA Privacy Rule’s “minimum necessary” provisions, described in 45 CFR 164.502(b) and 164.514(d). We believe that monthly data updates would align with a 90-day post-discharge episode window given the episode’s duration and the need to share data in a timely manner and identify areas for care improvement. Accordingly, we are proposing to make updated raw and summary beneficiary-identifiable claims data and regional aggregate data available for a given performance year to CJR–X participants upon receipt of a request for such information and execution of a CJR–X data sharing agreement with CMS, that meets CMS’s requirements to ensure the applicable HIPAA Privacy Rule conditions for disclosure have been met, as frequently as on a monthly basis during the performance year and continue sharing the claims data for up to 6 months beyond the end of that performance year to capture claims run out. We believe 6 months of claims run out is sufficient given that an internal review of Medicare claims data found that the majority of Medicare claims had been received, and were considered final, by 6 months after the date of service and is also consistent with how we are proposing claims run out for the reconciliation process, as described in section X.C.2.f.(5). of this proposed rule.<sup>487</sup>

To accomplish this for the first performance year of CJR–X, we would propose to provide, upon request and execution of a CJR–X data sharing agreement with CMS, and in accordance with the HIPAA Privacy Rule, beneficiary-identifiable claims data and aggregate regional data from October 1, 2027 to September 30, 2028 on as frequently as a running monthly basis, as claims are available. We would continue sharing beneficiary-identifiable claims data and regional aggregate data for episodes in

performance year 1 for an additional 6 months, so until March 31, 2029, to capture claims run out for items and services billed during this time period. These datasets would represent all potential episodes that were initiated in 2026 and capture sufficient amount of time, up to 6 months, for relevant claims to have been processed. We would limit the content of this data set to the minimum data necessary for the CJR–X participant to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. This data sharing process would continue each performance year of CJR–X. We considered proposing extending this period to capture more than 30 days of data or updating on a quarterly frequency. However, we do not believe this would benefit the CJR–X participant since it may create challenges to timely identify potential CJR–X beneficiaries for care coordination efforts. We seek comment on whether we should consider extending the period to capture more than 30 days of data or updating the data on a frequency other than as frequently as monthly.

We seek comments on this proposal at § 512.665(b)(6)(ii) and (d)(1)(ii) to make beneficiary-identifiable data and regional aggregate data available as frequently as a monthly basis and for up to 6 months after a performance year.

#### (6) CJR–X Data Sharing Agreement

We propose that if a CJR–X participant wishes to retrieve the beneficiary-identifiable data, the CJR–X participant would be required to first complete, sign, and submit—and thereby agree to the terms of—a data sharing agreement with CMS, which we would call the CJR–X data sharing agreement. We propose to define the “CJR–X data sharing agreement” as an agreement between the CJR–X participant and CMS that includes the terms and conditions for any beneficiary-identifiable data being shared with the CJR–X participant under § 512.665. Further, we propose to require CJR–X participants to comply with all applicable laws and the terms of the CJR–X data sharing agreement as a condition of retrieving the beneficiary-identifiable data. We also propose that the CJR–X data sharing agreement would include certain protections and limitations on the CJR–X participant’s use and further disclosure of the beneficiary-identifiable data and would be provided in a form and manner specified by CMS. Additionally, we propose that a TEAM Participant that wishes to retrieve the beneficiary-identifiable data would be required to

complete, sign, and submit a signed CJR–X data sharing agreement at least annually. We believe that it is important for the CJR–X Participant to complete and submit a signed CJR–X data sharing agreement at least annually so that CMS has up-to-date information that the CJR–X participant wishes to retrieve the beneficiary-identifiable data and information on the designated data custodian(s). As described in greater detail later in this section, we propose that a designated data custodian would be the individual(s) that a CJR–X participant would identify as responsible for ensuring compliance with all privacy and security requirements and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

We believe it is important for the CJR–X participant to first complete and submit a signed CJR–X data sharing agreement before it retrieves any beneficiary-identifiable data to help protect the privacy and security of any beneficiary-identifiable data shared by CMS with the CJR–X participant. There are important sensitivities surrounding the sharing of this type of individually identifiable health information, and CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with CJR–X participants would be further protected in an appropriate fashion.

We considered an alternative proposal under which CJR–X participants would not need to complete and submit a signed CJR–X data sharing agreement, but we concluded that, if we proceeded with this option, we would not have adequate assurances that the CJR–X participants would appropriately protect the privacy and security of the beneficiary-identifiable data that we are proposing to share with them. We also considered an alternative proposal under which the CJR–X participant would need to complete and submit a signed TEAM data sharing agreement only once for the duration of the CJR–X. However, we concluded that this similarly would not give CMS adequate assurances that the CJR–X participant would protect the privacy and security of the beneficiary-identifiable data from CMS. We concluded that it is critical that we have up-to-date information and designated data custodians, and that requiring the CJR–X participant to submit an CJR–X data sharing agreement at least annually would represent the best means of achieving this goal.

We solicit public comment on our proposal to define “CJR–X data sharing agreement” at § 512.605. We also seek comment on our proposal to require, in

<sup>487</sup> Medicare Claims Maturity: CCW White Paper accessed at [https://www2.ccwdata.org/web/guest/white-papers?p\\_l\\_back\\_url=%2Fweb%2Fguest%2Fsearch%3Fq%3Dmedicare%2Bclaims%2Bmaturity](https://www2.ccwdata.org/web/guest/white-papers?p_l_back_url=%2Fweb%2Fguest%2Fsearch%3Fq%3Dmedicare%2Bclaims%2Bmaturity) on Jan. 26, 2024.



§ 512.665(e)(2), that the CJR–X participant agree to comply with all applicable laws and the terms of the CJR–X data sharing agreement as a condition of retrieving the beneficiary-identifiable data, and on our proposal in § 512.665(e)(1) that the CJR–X participant would need to submit the signed CJR–X data sharing agreement at least annually if the CJR–X participant wishes to retrieve the beneficiary-identifiable data.

#### (a) Content of CJR–X Data Sharing Agreement

We are proposing that, under the CJR–X data sharing agreement, CJR–X participants would agree to certain terms, namely: (1) to comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA Privacy Rule and the requirements of the proposed CJR–X; (2) to comply with additional privacy, security, and breach notification requirements to be specified by CMS in the CJR–X data sharing agreement; (3) to contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the CJR–X participant or performs a similar function for the CJR–X participant, to the same terms and conditions to which the CJR–X participant is itself bound in its data sharing agreement with CMS as a condition of the downstream recipient's receipt of the beneficiary-identifiable data retrieved by the CJR–X participant under the CJR–X; and (4) that if the CJR–X participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the CJR–X data sharing agreement, the CJR–X participant would no longer be eligible to retrieve the beneficiary-identifiable data and may be subject to additional sanctions and penalties available under the law. We believe that these terms for sharing beneficiary-identifiable data with CJR–X participants are appropriate and important, as CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with CJR–X participants would be further protected by the CJR–X participant, and any business associates of the CJR–X participant, in an appropriate fashion. We believe that these proposals would allow CMS to accomplish that.

We seek public comment on the additional privacy, security, breach notification, and other requirements that we would include in the CJR–X data sharing agreement. CMS has these types

of agreements in place as part of the governing documents of other models tested under section 1115A of the Act and in the Medicare Shared Savings Program. In these agreements, CMS typically requires the identification of data custodian(s) and imposes certain requirements related to administrative, physical, and technical safeguards relating to data storage and transmission; limitations on further use and disclosure of the data; procedures for responding to data incidents and breaches; and data destruction and retention. These provisions would be imposed in addition to any restrictions required by law, such as those provided in the HIPAA Privacy, Security and Breach Notification Rules (45 CFR parts 160 and 164). These provisions would not prohibit the CJR–X participant from making any disclosure of the data otherwise required by law.

We also seek public comment on what disclosures of the beneficiary-identifiable data might be appropriate to permit or prohibit under the CJR–X data sharing agreement. For example, we are considering prohibiting, in the CJR–X data sharing agreement, any further disclosure, not otherwise required by law, of the beneficiary-identifiable data to anyone who is not a “HIPAA covered entity or business associate”, as defined in 45 CFR 160.103, or to an individual practitioner in a treatment relationship with the CJR–X beneficiary, or that practitioner's business associates. Such a prohibition would be similar to that imposed by CMS in other models tested under section 1115A of the Act in which CMS shares beneficiary-identifiable data with model participants.

We are considering these possibilities because there exist important legal and policy limitations on the sharing of the beneficiary-identifiable data and CMS must carefully consider the ways in which and reasons for which we would provide access to this data for purposes of the CJR–X. We believe that some CJR–X participants may require the assistance of business associates, such as contractors, to perform data analytics or other functions using this beneficiary-identifiable data to support the CJR–X participant's review of their care management and coordination, quality improvement activities, or clinical treatment of CJR–X beneficiaries. We also believe that this beneficiary-identifiable data may be helpful for any HIPAA covered entities who are in a treatment relationship with the CJR–X beneficiary.

We seek public comment on how a CJR–X participant might need to, and want to, disclose the beneficiary-

identifiable data to other individuals and entities to accomplish the goals of the CJR–X, in accordance with applicable law.

Under our proposal, the CJR–X data sharing agreement would include other provisions, including requirements regarding data security, retention, destruction, and breach notification. For example, we are considering including, in the CJR–X data sharing agreement, a requirement that the CJR–X participant designate one or more data custodians who would be responsible for ensuring compliance with the privacy, security and breach notification requirements for the data set forth in the CJR–X data sharing agreement; various security requirements like those found in other models tested under section 1115A of the Act, but no less restrictive than those provided in the relevant Privacy Act system of records notices; how and when beneficiary-identifiable data could be retained by the CJR–X-participant or its downstream participants of the beneficiary identifiable data; procedures for notifying CMS of any breach or other incident relating to the unauthorized disclosure of beneficiary-identifiable data; and provisions relating to destruction of the data. These are only examples and are not the only terms CMS would potentially include in the CJR–X data sharing agreement.

We solicit public comment on this proposal that CMS, by adding § 512.665(e)(1)(ii), would impose certain requirements in the CJR–X data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

Finally, we proposes, at § 512.665(e)(1)(iv), that the CJR–X data sharing agreement would include a term providing that if the CJR–X participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the CJR–X data sharing agreement, the CJR–X participant would no longer be eligible to retrieve beneficiary-identifiable data under proposed § 512.665(b) and may be subject to additional sanctions and penalties available under law. We also propose that if CMS determines that one or more grounds for remedial action specified in § 512.665(e)(iv) has taken place, CMS may discontinue the provision of data sharing and reports to the model participant. We propose that CMS may take remedial action if the model participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or

that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

We solicit public comment on this proposal, to prohibit the CJR-X participant from obtaining beneficiary-identifiable data pertaining to the CJR-X if the CJR-X participant fails to comply with applicable laws and regulations, the terms of the CJR-X, or the CJR-X data sharing agreement.

## 1. Alternative Payment Model Options

### (1) Background

As specified in the Quality Payment Program regulations (42 CFR 414.1415), in order to be considered an Advanced APM, an Alternative Payment Model (APM) must—

- Require use of Certified Electronic Health Record Technology (CEHRT);
- Be subject to payment based on quality measures; and
- Require entities to bear financial risk.

We seek to align the design of CJR-X with the Advanced APM criteria in the Quality Payment Program and enable CMS to have the necessary information on eligible clinicians to make the requisite Qualifying APM Participant (QP) determinations. Eligible clinicians, as defined at 42 CFR 414.1305, that are captured on a CMS-maintained list constituting an affiliated practitioner list, as defined at 42 CFR 414.1305, may be eligible to receive benefits for participating in an Advanced APM, including burden reduction and financial incentives. We propose that the CJR-X participant would be considered the APM entity, as defined at 42 CFR 414.1305, and that the CJR-X participant's affiliated practitioners, as defined at 42 CFR 414.1305, may be assessed for QP determinations depending on whether the CEHRT criteria are met, as established at 42 CFR 414.1425(b)(2). Additionally, we seek to ensure the design of CJR-X meets the Merit-based Incentive Payment System (MIPS) APM criteria and that CMS has the necessary information on MIPS eligible clinicians, as defined in 42 CFR 414.1305, so that they may be eligible for certain scoring benefits under MIPS. We therefore propose to adopt two different APM options for CJR-X—an “AAPM option” would be defined as an option in which CJR-X participants would attest to meeting the CEHRT requirement and in which the CJR-X participant's eligible clinicians may be assessed for QP determinations (to the extent CJR-X is determined to be an Advanced APM), and a “non-AAPM option” would be defined as an option in which CJR-X

participants would not meet CEHRT and in which the CJR-X participant's MIPS eligible clinicians may be assessed for reporting and scoring through the APM Performance Pathway (APP) (to the extent the CJR-X is determined to be a MIPS APM).

### (2) APM Options

As previously stated, an Advanced APM must require participants to use CEHRT (42 CFR 414.1415(a)), make payment based on quality measures (42 CFR 414.1415(b)) and meet financial risk standards (42 CFR 414.1415(c)). We propose two APM options in CJR-X: a non-Advanced APM (non-AAPM) option and an Advanced APM (AAPM) option. The non-AAPM option would be for CJR-X participants that do not meet the CEHRT. However, these CJR-X participants may still be considered APM entities in a MIPS APM. The AAPM option would be for CJR-X participants that meet the CEHRT requirement. These CJR-X participants would be considered APM entities in an Advanced APM.

We propose to require CJR-X participants who wish to participate in the AAPM option to attest to meeting the CEHRT use requirement that meets the CEHRT definition in our regulations at 42 CFR 414.1305 on an annual basis prior to the start of each performance year in a form and manner and by a date specified by CMS. We propose that the CJR-X participant would be required to retain and provide CMS access to the attestation upon request. We further propose that meeting and attesting to the CEHRT use criteria would be voluntary, and that CMS would assign CJR-X participants who choose not to do so to the non-AAPM option. Lastly, we propose to require CJR-X participants who wish to participate in the AAPM option to provide their CMS Electronic Health Record (EHR) Certification IDs on an annual basis prior to the end of each performance year in a form and manner and by a date specified by CMS.

We believe that a CJR-X participant's decision to meet and attest to the CEHRT use criteria would not create significant additional administrative burden for the CJR-X participant. Moreover, the choice of whether to meet and attest to the CEHRT use criteria would not otherwise affect the CJR-X participant's requirements or opportunities under the model. However, a CJR-X participant's decision to attest to CEHRT use may affect the ability of its clinicians to qualify as a QP. In other words, if a CJR-X participant chose not to attest to CEHRT

use, its clinicians would not be assessed for QPs status.

We seek comment on our proposals for the CJR-X Advanced APM options and the associated requirements at § 512.615. We also seek comment on our proposed definitions for the “AAPM option” and “non-AAPM option” at § 512.605.

### (3) Financial Arrangements List and Clinician Engagement List

We propose that each CJR-X participant would be required to submit information about the eligible clinicians or MIPS eligible clinicians who enter into financial arrangements with the CJR-X participant for purposes of supporting the CJR-X participants' cost or quality goals as discussed in section X.C.2.i. of this proposed rule. This information would enable CMS to make determinations as to eligible clinicians who could be considered for QP determinations based on the services furnished under CJR-X (to the extent the model is determined to be an AAPM) and would be necessary for APP reporting and scoring for MIPS eligible clinicians (to the extent the model is determined to be a MIPS APM). We are proposing that for purposes of CJR-X, the eligible clinicians or MIPS eligible clinicians could be: (1) CJR-X collaborators, as described in section X.C.2.i.(3). of this proposed rule, engaged in sharing arrangements with a CJR-X participant; (2) PGP, NPPGP, or TGP members who are collaboration agents engaged in distribution arrangements with a PGP, NPPGP, or TGP that is a CJR-X collaborator, as described in section X.C.3.i.(5) of this proposed rule; or (3) PGP, NPPGP, or TGP members who are downstream collaboration agents engaged in downstream distribution arrangements with a PGP, NPPGP, or TGP that is also an ACO participant in an ACO that is a CJR-X collaborator, as described in section X.C.3.i.(6). of this proposed rule. The list of physicians and nonphysician practitioners in these three groups that we are proposing to require CJR-X participants to submit to CMS would satisfy the criteria to be considered an Affiliated Practitioner List, as defined in 42 CFR 414.1305. We propose to use the list submitted by CJR-X participants to make determinations regarding which physicians and nonphysician practitioners should receive QP determinations or be reported for the APP based on the services they furnish under CJR-X.

We propose for the reasons detailed previously that each CJR-X participant with eligible clinicians or MIPS eligible clinicians must submit to CMS a

financial arrangements list in a form and manner and by the date specified by CMS on a quarterly basis during each performance year or attest that there are no individuals to report on the financial arrangements list. We believe submission of the financial arrangements list on a quarterly basis would align with the Quality Payment Program's QP determination dates, as described in 42 CFR 414.1425. We are proposing to define the "financial arrangements list" at § 512.605 as the list of eligible clinicians or MIPS eligible clinicians that have a financial arrangement with the CJR-X participant, CJR-X collaborator, collaboration agent, or downstream collaboration agent. We propose the CJR-X participant would be required to retain and provide CMS access to the financial arrangements list upon request. The proposed list must include the following information:

- For each CJR-X collaborator who is a physician, nonphysician practitioner, or therapist during the performance year—

- ++ The name, tax identification number (TIN), and national provider identifier (NPI) of the CJR-X collaborator; and

- ++ The start date and, if applicable, end date, for the sharing arrangement between the CJR-X participant and the CJR-X collaborator.

- For each collaboration agent who is a physician, nonphysician practitioner, or therapist during the performance year—

- ++ The name, TIN, and NPI of the collaboration agent and the name and TIN of the CJR-X collaborator with which the collaboration agent has entered into a distribution arrangement; and

- ++ The start date and, if applicable, end date, for the distribution arrangement between the CJR-X collaborator and the collaboration agent.

- For each downstream collaboration agent who is a physician or nonphysician practitioner, or therapist during the performance year—

- ++ The name, TIN, and NPI of the downstream collaboration agent and the name and TIN of the collaboration agent; and

- ++ The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.

- If there are no individuals that meet the reporting criteria listed previously for CJR-X collaborators, collaboration agents, or downstream collaboration agents, then the CJR-X participant must attest on a quarterly basis in a form and manner and by a date specified by CMS

that there are no individuals to report on the financial arrangements list. While the proposed submission of the financial arrangements list may create some additional administrative burdens for certain CJR-X participants, we expect that CJR-X Participants could modify their contractual relationships with their CJR-X collaborators and, correspondingly, require those CJR-X collaborators to include similar requirements in their contracts with collaboration agents and in the contracts of collaboration agents with downstream collaboration agents.

We also recognize there may be physicians and nonphysician practitioners who would not be listed on the financial arrangements list because they have not entered into a financial arrangement as a CJR-X collaborator, collaboration agent, or downstream collaboration agent, but who may nevertheless participate in CJR activities, as defined at proposed § 512.605, and may be eligible for QP determinations or eligible for APP reporting because they are affiliated with and support the APM Entity. We propose that, in order to capture these physicians and nonphysician practitioners who are not listed on the CJR-X participant's financial arrangements list for QP determinations or APP reporting, CJR-X participants must also submit to CMS a clinician engagement list in a form and manner and by a date specified by CMS on a quarterly basis every performance year. We propose to use the clinician engagement list for assessing QP determinations and for APP reporting. The submission of the clinician engagement lists may create some additional administrative burdens for CJR-X participants, but we expect the effort to be worthwhile since some of these QP determinations may result in eligible clinicians receiving burden reduction benefits and financial incentives, and some MIPS eligible clinicians may receive MIPS APM scoring benefits.

We propose to define the "clinician engagement list" at § 512.605 as the list of eligible clinicians or MIPS eligible clinicians that participate in CJR-X activities, have a contractual relationship with the CJR-X participant, and who are not listed on the financial arrangements list. We propose that the CJR-X participant must submit the list to CMS on a quarterly basis during each performance year in a form and manner and by a date specified by CMS or attest that there are no individuals to report on the clinician engagement list. We believe submission of the clinician engagement list on a quarterly basis

would align with the Quality Payment Program's QP determination dates, as described in 42 CFR 414.1425. We propose the CJR-X participant would be required to retain and provide CMS access to the clinician engagement list upon request. We propose that the clinician engagement list must include the following information:

- For each physician, nonphysician practitioner, or therapist who is not listed on the CJR-X participant's financial arrangements list during the performance year, but who does have a contractual relationship with the CJR-X participant and participates in CJR-X activities during the performance year—

- ++ The name, TIN, and NPI of the physician, nonphysician practitioner, or therapist; and
- ++ The start date and, if applicable, end date, for the contractual relationship between the physician, nonphysician practitioner, or therapist and the CJR-X participant.

- We are proposing that if there are no individuals that meet the requirements to be reported on the clinician engagement list, then the CJR-X participant must attest on a quarterly basis in a form and manner and by a date specified by CMS that there are no individuals to report on the clinician engagement list.

We seek comments on the proposal to require CJR-X participants to submit a financial arrangements list and clinician engagement list on a quarterly basis or attest that there are no individuals to report. We are especially interested in comments about approaches to information submission, including the content of the lists, and periodicity and method of submission to CMS that would minimize the reporting burden on CJR-X participants while providing CMS with sufficient information about eligible clinicians to facilitate QP determinations and APP reporting to the extent that CJR-X is considered to be an Advanced APM and a MIPS APM.

#### m. Standard Provisions

CJR-X meets the criteria for application of the Standard Provisions for Mandatory Innovation Center Models (42 CFR part 512, subpart A). Unless otherwise specified, all CJR-X participants and CJR-X beneficiaries would be subject to the provisions at §§ 512.100 through 512.190, which address the following areas:

- Beneficiary Protections.
- Cooperation in Model Evaluation and Monitoring.
- Audits and Record Retention.
- Rights in Data and Intellectual Property.
- Monitoring and Compliance.

- Remedial Action.
- Innovation Center Model Termination by CMS.
- Limitations on Review.
- Miscellaneous Provisions on Bankruptcy and Other Notifications.
- Reconsideration Review Process.

We recognize the standard provisions were not intended to encompass all the terms and conditions that would apply to each Innovation Center model, because each model embodies unique design features and implementation plans that may require additional, more tailored provisions, including with respect to payment methodology, care delivery and quality measurement, that would continue to be included in each model's governing documentation. Thus, we seek public comment on whether CJR-X should set forth model-specific provisions related to any of the provisions identified previously.

#### n. Termination of CJR-X

The general provisions relating to termination of the model by CMS in § 512.165 would apply to CJR-X. Consistent with termination provisions of other Innovation Center models, in the event we terminate CJR-X, we would provide written notice to CJR-X participants specifying the grounds for termination and the effective date of such termination or ending. As provided by section 1115A(d)(2) of the Act, termination of the model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

#### *D. Organ Acquisition and Reasonable Cost Payment Policies, and Reimbursement Appeals for Independent Organ Procurement Organizations and Histocompatibility Laboratories*

##### 1. Reconciliation of Organ Acquisition Costs for Non-Renal Organs for IOPOs and HCLs

###### a. Background

###### (1) Overview

Organ procurement organizations (OPOs)<sup>488</sup> perform or coordinate the procurement, preservation, and transportation of organs from deceased donors, and maintain a system for locating prospective recipients for organ transplantation. To participate in the Medicare program, OPOs must be members of the Organ Procurement and Transplantation Network (OPTN) and

must have agreements with hospitals or critical access hospitals in their service areas, to identify potential organ donors. OPOs provide both administrative and medical services that include, but are not limited to, arranging for tissue typing of donated organs; removal of the deceased donor organs (where the physicians are employed by the OPO or are under contract or agreement with the OPO); and perfusion, preservation, and transportation of the procured organs. OPOs may be independent or hospital-based. Hospital-based OPOs (HOPOs) are considered departments of their hospital and report costs for services on their transplant hospital's (TH's) Medicare cost report (MCR). Independent OPOs (IOPOs) file a separate cost report (see 42 CFR 413.420(c)(i)).

Histocompatibility laboratories (HCLs) are specialized clinical laboratories that perform tissue typing and compatibility testing on potential organ donors and recipients. These labs primarily conduct HLA (Human Leukocyte Antigen) typing—identifying tissue markers for organ and tissue transplantation. They perform crossmatching tests to determine compatibility between organ donors and recipients, antibody screening to detect antibodies that could cause transplant rejection, and disease association testing—HLA typing for certain autoimmune and genetic conditions. HCLs play a critical role in organ transplantation programs, ensuring that donated organs are matched appropriately with recipients to minimize rejection risk. HCLs may also be independent or hospital-based. Hospital-based HCLs are considered departments of their hospital and report costs for services on their TH's MCR. Independent HCLs, hereinafter referred to as HCLs, file a separate cost report (see 42 CFR 413.420(c)(i)).

Under section 1861(v)(1)(A), reasonable cost is the necessary cost actually incurred in the efficient delivery of needed health care services to Medicare beneficiaries. Section 413.1(a)(2)(v) identifies OPOs and HCLs as provider types to which part 413 of the regulations apply, making them expressly subject to Medicare's reasonable cost principles, including 42 CFR 413.9 regarding costs related to patient care. Currently, the Medicare program reimburses the reasonable costs related to patient care of allowable kidney acquisition services furnished by IOPOs and HCLs, provided that they have an agreement with the Secretary in accordance with 42 CFR 413.420. Kidney acquisition costs are not paid directly by Medicare to an IOPO or HCL.

IOPOs and HCLs are reimbursed for their kidney acquisition services by the THs, subject to later adjustment by Medicare (see 42 CFR 413.420). Medicare currently authorizes reimbursement to designated IOPOs for kidney acquisition costs, under reasonable cost principles<sup>489</sup> in accordance with section 1861(v) of the Act, based on the IOPO's ratio of Medicare usable kidneys to total usable kidneys (see section 1881(b)(2)(A) of the Act). Additionally, Medicare currently authorizes reimbursement to HCLs for the reasonable costs of pre-transplant kidney histocompatibility testing, based on the HCL's ratio of pre-transplant kidney histocompatibility charges to the total of HCL charges for all tests the lab performs, in accordance with section 1861(v) of the Act and 42 CFR 413.420. In accordance with 42 CFR 413.24(f), Medicare requires THs, IOPOs, and HCLs to complete an MCR<sup>490</sup> on an annual basis.

In the FY 2022 IPPS/LTCH PPS final rule with comment period, published in the **Federal Register** (FR) (86 FR 73468 through 73505) December 27, 2021, we clarified and codified certain Medicare organ acquisition payment policies in new subpart L of 42 CFR part 413. In the CY 2023 OPPS proposed rule (87 FR 44769 through 44773), published July 26, 2022, we included a request for information (RFI) and solicited comments that would help to inform potential changes to Medicare's organ acquisition payment policies. In the CY 2023 OPPS final rule (87 FR 72150 through 72159), published November 23, 2022, we clarified and codified certain other Medicare organ acquisition payment policies.

##### (2) Reimbursement of Organ Acquisition Costs

Medicare's current organ acquisition policy is modeled after the kidney acquisition policy that was implemented for kidney transplants following the Social Security Amendments of 1972 (Public Law 92–603) that extended Medicare coverage to individuals with end stage renal disease (ESRD) who required dialysis or transplantation. In July 1973 and July 1974, CMS (then the Bureau of Health Insurance<sup>491</sup> (BHI)) issued Intermediary

<sup>488</sup> Id. Section 1138(b)(1)(F) of the Act; 42 CFR 413.1(a)(1)(ii)(A); 413.420(a).

<sup>490</sup> THs complete the hospital cost report, form CMS–2552–10 (OMB No. 0938–0050) and IOPOs and HCLs complete cost report form CMS–216–94 (OMB No. 0938–0102).

<sup>491</sup> To implement the Medicare statute, the Social Security Administration was reorganized and the Bureau of Health Insurance (BHI) was established

<sup>488</sup> We refer to organ procurement organizations generally as “OPOs” throughout, unless differentiation of IOPO is required for cost reporting purposes, for OPOs that file a cost report on the CMS–216–94 (OMB No. 0938–0102).

Letters (ILs) which set forth procedures and policies for Medicare reimbursement for kidney transplants.<sup>492</sup> The IL 73–25 (July 1, 1973) set forth policies for the reimbursement of kidney transplants and dialysis, including policies for hospital reimbursement for the acquisition of a kidney from deceased and living donors for transplant into a Medicare beneficiary. The IL 74–23 (July 1974) addressed questions related to proper treatment for Medicare reimbursement purposes of various costs associated with kidney acquisition and transplant and kidney dialysis services. The IL 74–23 noted that the hospital is expected to acquire the kidney at a reasonably cost-related charge, which the hospital would pay to the organ procurement agency (now called organ procurement organization) and include as a cost to the TH.<sup>493</sup>

The Medicare reimbursement policies for IOPO and HCL kidney acquisition costs were implemented in a final rule (43 FR 58370 through 58372), published December 14, 1978. In that final rule, we noted that HOPOs or hospital-based HCLs included their services in their hospital cost report, and they were reimbursed based upon reasonable cost principles. However, THs had no authority or basis for determining the reasonableness of charges from IOPOs and independent HCLs, and the charges billed by IOPOs and these HCLs were not reviewed by the Medicare contractor (hereafter, “the contractor”) to determine reasonableness. As such, the potential existed for Medicare to pay more than reasonable costs for organ acquisition services. In June 1978, Congress passed Public Law 95–292 (the End Stage Renal Disease (ESRD) Program Amendment), which amended section 1881(b)(2)(A) of the Act, and required that reimbursement made under title XVIII for the services of OPOs and HCLs in procuring and furnishing organs for transplantation must not exceed the cost actually incurred by that OPO or HCL, and must be determined in accordance with section 1861(v) of the Act. Section 1861(v) of the Act requires that

payments be based upon reasonable costs.<sup>494</sup>

We note that Public Law 95–292 refers to the costs of procuring *organs*, thus including both kidneys and non-renal organs when requiring payments to be made at reasonable cost for the actual costs incurred. The legislative history of Public Law 95–292 indicates that Congress intended for the Secretary to apply already established principles of cost reimbursement, obtain periodic cost reports, and provide for an intermediary hearing for an IOPO or HCL which disagrees with a cost determination.<sup>495</sup> We believe that the legislative history also indicates that the cost of IOPO or HCL services would continue to be paid by the TH, but that the Secretary would be authorized to institute a system whereby IOPOs and HCLs could be reimbursed directly if such a system seems appropriate.<sup>496</sup>

We implemented section 1881(b)(2)(A) of the Act and this legislative intent by requiring that the Medicare program reimburse only the reasonable cost of IOPO and HCL services for kidney acquisitions.<sup>497</sup> We also required that the contractor establish IOPOs’ Standard Acquisition Charge (SAC) and HCL testing rates for kidney acquisitions. In addition, we required the contractor to review IOPOs’ and HCLs’ kidney acquisition costs and reconcile and settle those costs through the MCR. These measures were implemented to ensure that kidney acquisition costs would be paid on a reasonable cost basis, in accordance with the statute at sections 1881(b)(2)(A) and 1861(v) of the Act. We note that Medicare currently reconciles the organ acquisition costs incurred by HOPOs for all organs they procure, renal and non-renal, as part of the hospital cost report reconciliation.<sup>498</sup> Therefore, our discussion of reasonable cost for organ acquisition and cost reconciliation is focused on IOPOs and HCLs, but not HOPOs.

Over the years, through various rulings and national coverage determinations (NCDs), Medicare added coverage for transplantation of non-renal organs such as heart, liver, lungs, and pancreas. Non-renal organs were covered for transplantation through a

CMS Ruling (for heart transplants) and through NCDs (for other non-renal organs),<sup>499</sup> and payment policies were subsequently implemented through notice-and-comment rulemaking.<sup>500</sup> While we modeled our reimbursement for non-renal organ acquisition costs based on existing kidney acquisition policies, we did not address reasonable cost reimbursement and reconciliation of the non-renal organs to IOPOs and HCLs. Non-renal organ acquisition charges are billed to THs, and THs have no basis for determining the reasonableness of the charges from the IOPOs and HCLs, as previously noted, creating opportunity for Medicare to pay more than reasonable costs for these services (43 FR 58370).

Currently IOPOs determine their charges for non-renal organ acquisition costs and those amounts are billed to and paid by THs. THs subsequently include those charges in their organ acquisition costs without the ability for determining reasonableness. We are concerned about reports from our Medicare contractor and from the OIG<sup>501</sup> that IOPOs inflate their non-renal charges and exceed their reasonable costs for procurement services. IOPO cost report data for annual cost reporting periods ending in 2024<sup>502</sup> showed that non-renal organ revenue exceeded non-renal organ acquisition costs by \$100 million. OPOs are required to operate as non-profit organizations<sup>503</sup> under Federal regulations and to only recover their reasonable costs associated with organ procurement activities. The fundamental principle is that human organs are donated gifts, not commodities for sale. While OPOs can recover their reasonable and necessary

<sup>499</sup> See CMS Ruling 87–1, April 1987; National Coverage Determinations Manual, IOM 100–03, chapter 1, Part 4, section 260 (available at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1\\_Part4.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf)).

<sup>500</sup> 52 FR 33034, September 1, 1987 (heart); 55 FR 8545, March 8, 1990, and 56 FR 15013, April 12, 1991 (liver); 60 FR 6537, February 2, 1995 (lung); 64 FR 41497, July 30, 1999 (pancreas); 66 FR 39828, August 1, 2001 (intestine, with reasonable cost coverage of acquisition costs beginning October 1, 2001)."

<sup>501</sup> <https://oig.hhs.gov/documents/audit/9634/A-09-21-03020-Complete%20Report.pdf>, page 14.

<sup>502</sup> 42 CFR 413.20(b) requires that cost reporting periods are based on the provider's accounting year. In this analysis, 77 percent of IOPOs have a January 1–December 31 accounting year; 11 percent have a July 1–June 30 accounting year; 9 percent have an October 1 to September 30 accounting year; and the remaining 3 percent have a June 1–May 31 accounting year.

<sup>503</sup> 42 U.S.C. 273(b)(1)(A).

on July 30, 1965. The BHI then became responsible for the development of health insurance policy before the creation of the Health Care Financing Administration (HCFA), later renamed the Centers for Medicare & Medicaid (CMS). CMS Milestones 1937–2015 (July 2015).

<sup>492</sup> <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2022-ipp-proposed-rule-home-page>.

<sup>493</sup> <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2022-ipp-proposed-rule-home-page>; see page 10 of IL 74–23.

<sup>494</sup> See sections 1882(b)(2)(A) and 1861(v) of the Act.

<sup>495</sup> 43 FR 58370 and 58371. See also S. Rep. No. 95–714, 95th Cong., 2d Sess. 12–13 (1978); H. Rep. No. 95–549, 95th Cong., 1st Sess., 14 (1977).

<sup>496</sup> 43 FR 58371.

<sup>497</sup> *Ibid.* Note that in 1978, the only organs Medicare covered for transplant were kidneys. As such, we did not address non-renal organ acquisition costs.

<sup>498</sup> PRM–2, chapter 40, section 4028.

operational costs, they cannot profit from the organs themselves.<sup>504</sup>

In accordance with our current requirements at § 413.404(c)(1), for each non-renal organ type, an IOPO is supposed to establish its organ-specific non-renal acquisition charges by estimating the reasonable and necessary organ acquisition costs it expects to incur, divided by the projected number of organs it expects to procure, in its cost reporting period. The existing cost report data enables the MAC to determine if those acquisition charges the IOPO establishes are higher than what the acquisition charges should have been based on costs actually incurred. When an IOPO establishes a non-renal acquisition charge that is higher than its reasonable costs actually incurred, and the IOPO bills that inflated charge to a TH (or other OPO), that inflated charge is reported by the TH (or other OPO) as an organ acquisition cost on its cost report, Medicare then shares in those inflated costs. To correct this situation and ensure IOPOs and HCLs are held to reasonable costs, similar to HOPOs and hospital-based HCLs, we are proposing to reconcile IOPO and HCL costs for non-renal organs similar to how we reconcile IOPO and HCL kidney costs. We are proposing to require that IOPO and HCL non-renal organ acquisition costs be reviewed and analyzed by the Medicare contractor to ensure those costs are reasonable, necessary, related to patient care, and reconciled to payments made by or payable by THs and other OPOs. Without reconciliation, reasonable costs cannot be determined for non-renal organs leading to inflated organ acquisition costs to the THs and inflated costs throughout the transplant ecosystem.

#### b. Proposal To Reconcile Non-Renal Organ Acquisition Costs for IOPOs and HCLs

Section 413.420(a)(1) explains that covered services furnished by IOPOs and HCLs in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost. As noted previously, section 1881(b)(2)(A) of the Act was amended in 1978 to require that reimbursement for the services of OPOs and HCLs in procuring and furnishing organs for transplantation must not exceed the cost actually incurred by that OPO or HCL. We also noted that HOPOs and hospital-based HCLs are reimbursed under reasonable cost principles for their services through the hospital cost

report. Lastly, we noted that over the years, through various rulings and NCDs, Medicare added coverage for transplantation of non-renal organs such as heart, liver, lungs, and pancreas and payment policies were subsequently implemented through notice-and-comment rulemaking. While we modeled our reimbursement for non-renal organ acquisition costs based on existing kidney acquisition policies, we did not address reasonable cost reimbursement and reconciliation of the non-renal organs for IOPOs and HCLs.

In this proposed rule, we are proposing to hold IOPOs and HCLs to reasonable cost reimbursement for organ acquisition and transplantation services in accordance with section 1861(v) of the Act. We are proposing to revise the title of § 413.420 to change “kidney” to “organ” and to define the acronym IOPOs after independent organ procurement organizations and the acronym HCLs after histocompatibility laboratories. Throughout § 413.420, we also propose to use the acronym HCL and its permutations in every title, paragraph, or subparagraph where a histocompatibility laboratory or laboratory, and their various permutations, are mentioned. This would revise the regulation text at § 413.420(a)(1), (a)(2), (c) paragraph heading, (c)(1), (c)(1)(ii), (c)(1)(iv), (c)(2), (d)(1) through (d)(4), (e)(1), (e)(1)(i), (e)(2), (e)(2)(ii), and (g).

In addition, we are proposing to revise 42 CFR 413.420(a)(1) and to add paragraphs (a)(1)(i) and (ii). Specifically, we are proposing to revise § 413.420(a)(1) to specify that covered services furnished by IOPOs and HCLs in connection with organ acquisition and transplantation are reimbursed under the principles for determining reasonable cost as specified in paragraphs (a)(1)(i) and (ii). We are also proposing to add § 413.420(a)(1)(i) to specify that kidney acquisition and transplantation services furnished by IOPOs and HCLs are reimbursed under the principles for determining reasonable cost. For non-renal organs, we are proposing to add § 413.420(a)(1)(ii) to specify that for non-renal organ acquisition and transplantation services furnished for cost reporting periods beginning on or after October 1, 2027,<sup>505</sup> IOPOs and HCLs are reimbursed under the principles for determining reasonable cost. This includes a proposed delay in implementation which would allow us

time to update the IOPO and HCL cost reporting form CMS–216–94, OMB control number 0938–0102. The delay would also allow IOPOs and HCLs time to prepare to implement the changes from the new policy.

We are proposing to revise § 413.420(a)(2) to include OPOs as payors of IOPOs and HCLs and to specify that services furnished by IOPOs and HCLs that have an agreement with the Secretary, in accordance with § 413.420(c), are paid directly by the TH or OPO using a kidney SAC (for an IOPO) or contractor-established rates (for an HCL). Under this proposal, we would also specify that the reasonable costs of services furnished by IOPOs or HCLs are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.

Section 413.420(c), (which concerns agreements with IOPOs and HCLs, currently specifies that any IOPO or HCL that wishes to have the cost of its pre-transplant services reimbursed under the Medicare program must file an agreement with CMS under which the IOPO or HCL agrees to the following:

- To file a cost report in accordance with § 413.24(f) within 5 months following the close of the period covered by the report.
- To permit CMS to designate a contractor to determine the interim reimbursement rate, payable by the THs for services provided by the IOPO or HCL, and to determine Medicare’s reasonable cost based upon the cost report filed by the IOPO or HCL.
- To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate.
- To pay to CMS amounts that have been paid by CMS to THs and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or HCL.
- Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1881 of the Act.

Because of the proposed change to the title of § 413.420, paragraph (c) would apply to both kidney and non-renal organs. We propose to revise § 413.420(c)(1)(ii) to include OPOs as entities that pay IOPOs and HCLs. We also propose to revise § 413.420(c)(1)(iv) to specify that the IOPO or HCL agrees to pay to CMS amounts that have been received or are receivable by IOPOs or HCLs from THs and OPOs, and that are in excess of the reasonable costs of the services provided by the IOPO or HCL. This rephrasing to use “have been received or are receivable” reflects the

<sup>505</sup> We realize reconciliation for non-renal organs will require changes to the MCR form CMS–216–94, as well as procedural changes for IOPOs, HCLs and the Medicare contractor. Therefore, we are proposing a one-year delay.

<sup>504</sup> Pub. Law 98–507, National Organ Transplant Act, Section 301.

accrual basis of accounting required at § 413.24(a) and reflects that the payments are made to IOPOs and HCLs by THs and OPOs.

Section 413.420(d)(1) currently specifies that THs with approved kidney transplant programs pay the IOPO or HCL for their pre-transplantation services on the basis of interim rates established by the contractor for that IOPO or HCL. The authority to allow the contractor to establish the interim rate is described in § 413.420(c)(ii). The interim rate currently described in § 413.420(d)(2) is a kidney SAC or contractor established rates, based on costs associated with procuring a kidney for transplantation, incurred by an IOPO or HCL respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it according to the IOPO's or HCL's estimate of its projected costs for the fiscal year. Section 413.420(d)(3) goes on to specify that payments made by THs on the basis of interim rates are reconciled directly with the IOPO or HCL after the close of its fiscal year, in accordance with § 413.420(e). Lastly, § 413.420(d)(4) currently specifies that information on the interim rate for all IOPOs and HCLs must be disseminated to all THs and contractors.

In accordance with § 413.420(c)(ii), and to ensure that non-renal SACs and non-renal testing rates are an accurate estimate of actual costs, and to increase transparency around non-renal SACs and non-renal testing rates, we further propose to require the contractor to establish (and adjust if necessary) non-renal SACs. This proposed change also requires conforming changes to § 413.420(d)(1). As noted previously, § 413.420(d)(1) specifies that THs with approved kidney transplant programs pay the IOPO or HCL for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or HCL. However, we propose to revise § 413.420(d)(1) to specify that THs with approved transplant programs and OPOs pay the IOPO or HCL for their pre-transplantation services based on interim rates established by the contractor for that IOPO or HCL as described under proposed paragraphs (d)(1)(i) and (d)(1)(ii). OPOs are also entities that pay IOPOs and HCLs for their pre-transplant services using the interim rates.

We propose to add § 413.420(d)(1)(i) to specify that THs with approved kidney transplant programs and OPOs pay the IOPO or HCL for their kidney pre-transplantation services, based on interim rates established by the

contractor for that IOPO or HCL. In addition, we propose to add § 413.420(d)(1)(ii) to specify that THs with approved non-renal transplant programs and OPOs pay the IOPO or HCL for their non-renal organ pre-transplantation services furnished for cost reporting periods beginning on or after October 1, 2027, based on interim rates established by the contractor for that IOPO or HCL. The establishment of these interim rates is the first step in preparing for the reconciliation for non-renal organ acquisition costs.

Section 413.420(d)(2) currently provides that the interim rate established by the contractor for an IOPO is a kidney SAC, and the interim rates established for an HCL are contractor established rates, based on costs associated with procuring a kidney for transplantation, and incurred by an IOPO or HCL during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it according to the IOPO's or HCL's estimate of its projected costs for the fiscal year. We propose that the contractor follow the same procedures for establishing, adjusting, and publishing non-renal SACs that are used for establishing, adjusting, and publishing kidney SACs. To implement this proposed change, we are proposing to revise § 413.420(d)(2) and to add paragraphs (d)(2)(i) and (ii).

We are proposing to revise § 413.420(d)(2) to specify that interim rates are contractor established rates, based on costs associated with procuring an organ for transplantation, incurred by an IOPO or HCL during its previous fiscal year as described under proposed § 413.420(d)(2)(i) and (ii). We are also proposing to move language specific to kidney from the existing § 413.420(d)(2) to proposed § 413.420(d)(2)(i) and to specify that the interim rates for kidneys are a contractor established kidney SAC or contractor established rates, associated with procuring kidneys for transplantation, incurred by an IOPO or HCL, respectively, during its previous fiscal year. Under our proposal, if there is not adequate cost data to determine the initial interim rate, the contractor would determine it according to the IOPO's or HCL's estimate of its projected costs for the fiscal year.

Rates for non-renal organs are currently established by the IOPOs and HCLs in accordance with § 413.404(c)(1) and billed to THs or other OPOs. THs and OPOs pay the rates established by these entities; however, there is no ability for the THs or other OPOs to determine the reasonableness of these rates. We propose that the contractor

establish, adjust (if necessary), and publish the non-renal organ interim rates for IOPOs and HCLs. Our proposal would ensure compliance with reasonable cost principles, result in lower costs throughout the transplant ecosystem, enhance payment accuracy, provide financial protection to OPOs and HCLs for their reasonable costs, increase transparency surrounding costs, and provide robust oversight in response to Congressional and OIG concerns. Therefore, we are proposing to add § 413.420(d)(2)(ii) to specify that for services furnished for cost reporting periods beginning on or after October 1, 2027, the interim rates for non-renal organs are contractor established non-renal organ-specific SACs or contractor established rates, based on costs associated with procuring each specific type of non-renal organ for transplantation, incurred by an IOPO or HCL, respectively, during its previous fiscal year. Under our proposal, if there is not adequate cost data to determine the initial interim rates, the contractor would determine them according to the IOPO's or HCL's estimate of its projected costs for the fiscal year.

Section 413.420(d)(3) currently specifies that payments made by THs based on interim rates are reconciled directly with the IOPO or HCL after the close of its fiscal year, in accordance with § 413.420(e). We are proposing to revise § 413.420(d)(3) to specify that payments or amounts payable from THs and OPOs based on interim rates as proposed in § 413.420(d)(2)(i), are reconciled directly with the IOPO or HCL after the close of its fiscal year in accordance with § 413.420(e). Additionally under § 413.420(d)(3), we are proposing to specify that for cost reporting periods beginning on or after October 1, 2027, payments or amounts payable from THs and OPOs based on interim rates as proposed in § 413.420(d)(2)(ii), are reconciled directly with the IOPO or HCL after the close of its fiscal year in accordance with § 413.420(e).

We propose to revise § 413.420(d)(4) to change "interim rate" to "interim rates" and to specify that when a contractor establishes interim rates for IOPOs and HCLs, it must disseminate those interim rates to all THs, OPOs, and contractors. Our proposed language adds OPOs to the list of entities that would receive the interim rate information since OPOs also pay IOPOs for organs.

We did not propose changes to § 413.420(e)(1) except to use the acronym HCLs instead of "histocompatibility laboratories" because the existing language specifies



cost reporting requirements that are unchanged, and which apply to IOPOs and HCLs currently and would continue to apply once our proposed changes would be effective.

We did not propose to revise § 413.420(e)(2) except to use the acronym HCL instead of “histocompatibility laboratory” as this paragraph applies to the current policy. We propose to revise § 413.420(e)(2)(i) to add the word “kidney” before “interim rate” to be clearer that this regulation applies to the existing policy. We also propose to revise the sentence to reflect the accrual basis of accounting required at § 413.24(a) by specifying that a retroactive adjustment of the amounts received or receivable by the IOPO or HCL under the kidney interim rate is made in accordance with § 413.64(f).

We propose to revise § 413.420(e)(2)(ii) to add the word “kidney” before “interim reimbursement rate” to be clearer that this regulation applies to the existing policy. We also propose to revise the sentence to reflect the accrual basis of accounting required at § 413.24(a), and to include OPOs as entities that pay IOPOs and HCLs. Therefore, we propose to specify that if the determination of reasonable cost reveals an overpayment or underpayment resulting from the kidney interim reimbursement rates received or receivable by the IOPO or HCL from THs and OPOs, a lump sum adjustment is made directly between the contractor and the IOPO or HCL.

We propose to add § 413.420(e)(3) to specify that for cost reporting periods beginning on or after October 1, 2027, a cost report submitted by an IOPO or HCL is reviewed by the contractor and new interim reimbursement rates for non-renal organ acquisition costs for the subsequent fiscal year are established by the contractor based upon this review. This proposed language is similar to the existing language at § 413.420(e)(2) except it includes the effective date of the proposed new policy and refers to non-renal organ acquisition costs rather than kidney acquisition costs.

We propose to add § 413.420(e)(3)(i) to specify that a retroactive adjustment of the amounts received or receivable by the IOPO or HCL under the non-renal organ-specific interim rates is made in accordance with § 413.64(f). This proposed language is similar to the existing language at § 413.420(e)(2)(i) except it refers to the “non-renal organ-specific interim rates” rather than the “interim rate” to reflect our proposed policy and also refers to amounts “received or receivable” to reflect the accrual basis of accounting required at § 413.24(a).

We propose to add § 413.420(e)(3)(ii) to state that if the determination of reasonable cost reveals an overpayment or underpayment resulting from the non-renal organ-specific interim reimbursement rates received or receivable by the IOPO or HCL from THs and OPOs, a lump sum adjustment is made directly between the contractor and the IOPO or HCL. This proposed language refers to non-renal organ-specific interim reimbursement rates rather than kidney interim reimbursement rates to reflect the proposed policy. It also indicates that payments are received or receivable by IOPOs or HCLs from THs and OPOs to reflect our reconciliation process, which is in accordance with the accrual basis of accounting required at § 413.24(a), and it identifies both THs and OPOs as the entities paying IOPOs and HCLs.

We are also proposing changes to § 413.404 to conform to the changes proposed to § 413.420(d), which require the contractor to establish the non-renal organ-specific interim rates, which are the same as the non-renal organ-specific SACs, following the same procedures used for establishing kidney SACs. We also propose that only the contractor adjust the non-renal SACs if necessary, and that the contractor disseminate the interim rates to all THs, OPOs, and contractors.

As noted previously, we are proposing a 1-year delay in implementing our proposed changes. Therefore, we need to indicate when these regulations would be effective. As such, we are proposing to change the title of § 413.404(c) to specify that it is for cost reporting periods beginning before October 1, 2027. This proposed change would clarify for readers that all the existing regulatory text under § 413.404(c) is effective for cost reporting periods beginning before October 1, 2027. We also propose to add new § 413.404(d) with a title that specifies that it is for Independent OPO organ SACs, for cost reporting periods beginning on or after October 1, 2027, and which would incorporate our proposed changes. This new paragraph (d) is for all organs, renal and non-renal.

We propose to add new § 413.404(d)(1), to state that for each organ type, the contractor establishes the organ-specific SAC based on an estimate of, initial year projected or subsequent years’ actual, reasonable and necessary costs that the IOPO expects to incur to procure deceased donor organs during the IOPO’s cost reporting period, divided by the initial year projected or subsequent years’ actual, number of usable deceased donor organs the IOPO expects to procure. This is modeled

after the existing kidney SAC regulations at § 413.404(c)(2)(i), except we propose to add “For each organ type,” at the start of the paragraph, and we replaced kidney SAC with organ-specific SAC and replaced deceased donor kidneys with deceased donor organs.

We also propose to add § 413.404(d)(1)(i) to specify how the non-renal and kidney SACs would be calculated in their initial year, by modelling after the existing regulation text at § 413.404(c)(2)(ii). The proposed text added at new § 413.404(d)(1)(i) would specify that for each organ type, the contractor develops the IOPO’s initial organ-specific SAC based on the IOPO’s budget information.

We also propose to add § 413.404(d)(1)(ii) to specify how the non-renal and kidney SACs would be calculated in subsequent years, by modelling after the existing regulation text at § 413.404(c)(2)(iii). The proposed § 413.404(d)(1)(ii) would state that for each organ type, the contractor computes the organ-specific SAC for subsequent years using the IOPO’s costs related to organ acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable deceased donor organs procured during that cost reporting period.

We propose to add § 413.404(d)(1)(iii), to state that each organ-specific SAC amount is the organ-specific interim payment the TH or other OPO pays to the IOPO, as set forth in § 413.420(d)(2)(i) and (ii). This language would make clear that the organ-specific SAC is the same as the organ-specific interim payment.

We also propose to add § 413.404(d)(1)(iv) to provide a listing of allowable organ acquisition costs for the contractor to use when establishing IOPO organ-specific SACs. In the FY 2022 IPPS/LTCH PPS final rule with comment period, we wrote that an IOPO establishes its non-renal SACs based on its costs of procuring organs, similar to procedures followed by transplant hospitals (86 FR 73478). However, the listing of organ acquisition costs IOPOs should use when developing their deceased donor SACs was omitted when we codified the regulations related to IOPO SACs in the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 73478 through 73480). Therefore, we are proposing to use the same listing given in § 413.404(b)(3)(ii)(C) for transplant hospital deceased donor SACs, except to exclude registry fees, which are costs incurred by THs not OPOs. We are proposing to add § 413.404(d)(1)(iv) to specify that costs



that may be used to develop the IOPO deceased donor SACs include, but are not limited to the following:

- Costs of organs acquired from other THs or OPOs.
- Costs of transportation as specified in § 413.402(b)(8).
- Surgeons' fees for excising deceased donor organs (limited to \$1,250 for kidneys).
- Costs of tissue typing services, including those furnished by independent laboratories.
- Organ preservation and perfusion costs.
- General routine and special care service costs (for example, intensive care unit or critical care unit services related to the donor).
- Operating room and other inpatient ancillary service costs.

We propose to add § 413.404(d)(1)(v) to require that only the contractor may adjust the organ SACs. This is a proposed change from the existing policy, where the IOPO currently can adjust its non-renal SACs as needed and use that adjusted SAC without contractor approval; we also included the word "only" to make it clear that only the contractor may adjust organ SACs. We also propose to state that IOPOs may request that the contractor make an adjustment in accordance with § 413.64(e), or the contractor may initiate an adjustment, in accordance with § 413.64(d)(2) or § 413.64(e) as applicable.

While we modelled our proposed regulation text after the existing regulations for IOPO kidney SACs, we did not propose to add a subparagraph (vi), similar to the existing regulation at § 413.404(c)(2)(vi), which currently states that the IOPO cannot use or change its kidney SAC without the contractor's approval. That language is not necessary because proposed subparagraph (v) already makes it clear that only the contractor can adjust the organ SACs, and any SAC the contractor establishes would already be contractor approved.

Finally, we are proposing to add § 413.404(d)(2) to state that when an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses its SAC for each organ type, and not the procuring IOPO's SAC, when billing the TH receiving the organ. This is the same as the existing requirement at § 413.404(c)(3), and we are continuing this policy without change.

To reconcile Medicare's share of non-renal organ acquisition costs, the contractor would review the MCR to determine if the costs are reasonable.

This would entail the contractor's review of all IOPO and HCL organ acquisition costs that IOPOs and HCLs report annually on their MCRs and would ensure that IOPOs' and HCLs' organ acquisition costs are allowable and are reasonable and necessary, in accordance with section 1861(v) of the Act, the regulations, and Provider Reimbursement Manual (PRM), CMS Pub. 15–1 (herein referred to as PRM–1).<sup>506</sup>

In determining Medicare's share of non-renal organ acquisition costs, we propose that IOPOs and HCLs would follow the same procedures used for kidney reconciliation, which assumes that all usable organs or tests for usable organs intended for transplant are for Medicare beneficiaries, except for usable organs, or tests for usable organs, sent to military hospitals, U.S. Department of Veterans Affairs hospitals, or foreign countries. We believe that even with this limitation, our proposal would rein in excess costs; provide more robust oversight of IOPO and HCL costs; increase payment accuracy, in accordance with reasonable cost principles; and be responsive to Congressional and OIG concerns. Should this proposal be finalized, we would also update the IOPO and HCL cost report form CMS–216–94 to enable reconciliation of costs and revenues for each organ type.

#### c. Discussion of OPO Comments in Response to the July 2022 RFI on Non-renal Organ Acquisition Cost Reconciliation

In the CY 2023 OPPS/ASC proposed rule (87 FR 44769 through 44773), we issued an RFI (hereafter referred to as the "July 2022 RFI") and inquired about reconciling non-renal organ acquisition costs, mirroring our current approach for determining Medicare's reimbursement of IOPOs' kidney acquisition costs. We received several comments related to non-renal organ reconciliation and have carefully reviewed each one.

##### (1) Supportive Comments

We received a few comments to the July 2022 RFI from a TH, a patient advocacy group, and a provider of high-cost perfusion services supporting Medicare's non-renal SAC reconciliation. A commenter fully supported Medicare's non-renal reconciliation and wrote that the data show that many OPOs are failing in their organ recovery efforts; this

commenter wrote that the current reimbursement policies are insufficient to incentivize productive resource allocation. Several commenters supported additional oversight of IOPO non-renal organ acquisition costs, saying it would strengthen fiscal integrity. One commenter noted that the distinction between how we account for renal versus non-renal organ acquisition costs creates powerful incentives for cost shifting to kidney acquisition cost centers on the MCR. We agree with these commenters and thank them for their support.

##### (2) Effects on Organ Procurement

Other comments we received in response to the July 2022 RFI were from OPOs, OPO industry groups, or OPO consultants that expressed opposition to Medicare's reconciling non-renal organ acquisition costs. These commenters believed that reconciling non-renal organ acquisition costs would undercut their ability to procure marginal organs, leading to fewer organs and therefore fewer transplants. Specifically, some OPO commenters wrote that the costs of procuring, or attempting to procure, marginal organs that are subsequently found not suitable for transplant would create losses, as there would be no revenue from those organs. As such, these commenters wrote that they may have to scale back efforts to procure marginal organs. However, these commenters seemed to misunderstand Medicare's organ acquisition payment policy, which allows reasonable costs of procuring or attempting to procure an organ intended for transplant, even if it is subsequently found not suitable for transplant (see our regulations at § 413.412(a)(2) and (d)(2)). Medicare's reconciliation of organ acquisition costs for renal and non-renal organs would make IOPOs whole when total organ acquisition costs exceed total revenue, but this currently only occurs for kidneys.

In contrast to these OPO commenters, multiple other OPO commenters who also opposed Medicare's reconciling non-renal organ acquisition costs (because they were concerned about potential financial swings and the need to have large cash reserves) wrote that their procurement of organs would not be affected by such a policy, as they try to procure every organ, every time. Furthermore, several commenters stated that OPOs are incentivized to procure as many organs as possible through their organ performance metrics, which affect their tier rating. A perfusion provider commented that reconciling non-renal organs would increase organ procurement by removing the financial

<sup>506</sup> CMS Pub. 15–1 can be found at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929>.

risk if an organ is procured but subsequently not transplanted. We agree and further assert that Medicare's reconciliation of non-renal organs could *encourage* the pursuit of marginal organs by protecting OPOs from financial losses on marginal non-renal organs that are later found unsuitable for transplant, thus reinforcing our goal to support organ procurement and organ transplantation.

### (3) Costs for Organ Perfusion

Several commenters were concerned about situations where OPOs expend resources procuring organs that undergo costly interventions (for example, perfusion) but are later declined by THs and determined to be unsuitable for transplantation. One commenter wrote that if Medicare reconciles non-renal organ acquisition costs for IOPOs, those costly interventions would be considered unallowable, and the OPO would bear the cost. We disagree as our regulations at § 413.402(b)(5) allow perfusion costs; as noted previously, costs incurred for organs intended for transplant are allowable even if the organ is subsequently not transplanted (see §§ 413.412(a)(2) and 413.412(d)(2)). Therefore, if an IOPO authorized the perfusion of a non-renal organ intended for transplant that was subsequently not transplanted, those costs would be allowable (if a transplant hospital authorized the perfusion, the perfusion costs would belong to that transplant hospital and should be directly billed to that hospital). If Medicare reconciled IOPOs' costs for procuring all organs, it could reimburse more since it would cover acquisition costs for all organ types, not just kidneys as under the current policy.

### (4) "Losses" Due to Nonallowable Costs

Several commenters wrote that they have "losses" when procuring kidneys, because in reconciling, the contractor finds some costs that OPOs report on their MCRs to be unallowable. While OPOs can recover their allowable and reasonable operational costs, we cannot reimburse costs that are statutorily or regulatorily prohibited, or specified in the PRM-1 as non-allowable or unreasonable. In sections X.D.2. and X.D.3. of the preamble of this proposed rule, we are clarifying existing policy and proposing to codify certain longstanding reasonable cost policies, as well as revising certain other Medicare reasonable cost reimbursement policies, to assist all providers, including OPOs, in understanding what is not allowable under Medicare's reasonable cost principles.

Some commenters wrote that they make up for these monetary "losses" they experience when procuring kidneys through the revenue they receive for procuring non-renal organs. A few OPOs and industry groups acknowledged that their non-renal organ SACs result in "excess" revenue which they are using to fund non-allowable or unreasonable costs. That excess revenue is a result of inflated non-renal SACs, which are billed to transplant hospitals or other OPOs, inflating costs throughout the transplant ecosystem. Medicare ends up reimbursing its share of those inflated costs when it reimburses the TH, which violates our reasonable cost principles. We are committed to carefully and responsibly stewarding the tax dollars in the Medicare Trust Fund, and we believe that Medicare's reconciliation of OPOs' non-renal organ acquisition costs would result in Medicare more accurately reimbursing organ acquisition costs.

### (5) Burden

IOPOs indicated in comments submitted in response to the July 2022 RFI that they had concerns about the burden for IOPOs if Medicare reconciled IOPOs' costs for non-renal organs. We do not believe Medicare's reconciliation of IOPOs' costs for non-renal organs would impose additional data collection burden to IOPOs, as they already collect the data needed for reconciliation. However, we recognize there may be additional reporting burden to enable the contractor to reconcile non-renal organ acquisition costs.

A few OPOs also commented that there would be additional burden on the contractor if reconciliation of non-renal organs were to become policy. We do not agree that there would be additional burden on the contractor. Burden implies a cost that is not reimbursed. Our contractor would have increased administrative costs if we were to finalize our proposals that the contractor establish, adjust if necessary, and publish non-renal SACs and HCL testing rates, and reconcile IOPO and HCL non-renal organ acquisition costs. However, those administrative costs would be included in their contract. These increased administrative costs would be offset by the estimated savings of \$100 million beginning in FY 2028, the first year that the policies would be effective, if the proposal is finalized. See section I.G.13. of Appendix A of this proposed rule for a discussion of the impacts including burden effects of our proposals.

### (6) Financial Concerns

A few commenters to the July 2022 RFI wrote that if non-renal organ acquisition costs are reconciled, they would have to build large financial reserves in case they may have to repay Medicare a share of those excess funds. We believe that if IOPOs' SACs more accurately estimate actual, reasonable costs, then reconciliation would not result in large payments back to Medicare, therefore limiting the need for large financial reserves. We also note that SACs can be adjusted during the year if IOPOs believe they are too high or too low. This can help IOPOs avoid owing large sums to Medicare after the year-end reconciliation takes place in cases where the SAC is overestimating costs. If an IOPO's SACs were underestimated, and costs are exceeding revenue, the contractor can also provide a lump sum adjustment during the accounting period; currently this only occurs with the kidney SAC (see 42 CFR 413.420(e)(2)(ii)) but our proposal would also allow it for non-renal organ SACs. Any lump sum adjustment would be accounted for when making a retroactive adjustment at cost report settlement.

Other commenters wrote that Medicare's reconciliation of non-renal organs would have a detrimental effect on the financial viability of IOPOs and cited section 371(b) of the Public Health Service Act (PHSA), which requires OPOs to have accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization. These IOPOs were concerned about losing "excess" revenue. However, we believe that reconciliation is an accounting procedure that helps to ensure the financial integrity and stability of the IOPO or HCL and would be in accord with the requirements of section 371(b) of the PHSA by providing fiscal stability to the OPO. The reconciliation process for all non-renal organs would also entail the contractor's disseminating the non-renal SACs for each IOPO to THs, OPOs, and other contractors, thereby increasing transparency of organ procurement costs within the transplant community.

Commenters cited high-cost perfusion and transportation expenses that can make accurately estimating a non-renal SAC more difficult, leaving them vulnerable to financial losses. We conducted an analysis of 2024 IOPO MCR data and found that 20 percent of IOPOs had non-renal organ acquisition costs that exceeded their non-renal revenue; these IOPOs would have been made whole by Medicare had

reconciliation for non-renal organ acquisition costs been Medicare's policy at that time. We believe that reconciliation would provide a measure of financial security to IOPOs, because it would protect them from losses if their non-renal SACs underestimate non-renal organ acquisition costs. Furthermore, we believe that if Medicare were to reconcile OPOs' costs for non-renal organs, the Medicare Trust Fund's tax dollars would be protected from inappropriate spending on unreasonable or non-allowable costs.

We appreciate the input we received from July 2022 RFI commenters. For the reasons given in this section, we do not find the interested parties' concerns against reconciling IOPOs' non-renal organ acquisition costs to be compelling. We believe that reconciling IOPOs' non-renal organ acquisition costs would ensure that Medicare is paying organ acquisition costs on a reasonable cost basis, without hindering organ procurement. We also believe there is a need for the contractor to provide more robust oversight of IOPOs' non-renal organ acquisition costs and non-renal SACs to ensure that reasonable cost principles are followed, to be responsive to OIG and Congressional concerns, to protect the transplant ecosystem, and to protect the Medicare Trust Fund.

#### d. Concerns Related to HCLs

Like IOPOs, HCLs are compensated on a reasonable cost basis, and currently Medicare only reconciles their pre-transplant kidney histocompatibility testing costs. Based on our review of HCL MCR data, we have concerns that some HCLs may be over-allocating overhead costs to kidney acquisition cost centers, which increases Medicare's reimbursement. Additionally, a 2018 OIG report identified questionable accounting procedures at a large HCL. This HCL made numerous errors in reporting cost report data, such as reporting some non-reimbursable costs as reimbursable and including costs that were incurred outside of the cost reporting timeframe.<sup>507</sup> A recent internal review of 2022 and 2023 MCR data for HCLs revealed missing data and a lack of transparency in reporting costs. For example, 29 percent of HCLs did not complete worksheet A-1 ("Administrative and General (A&G) Expenses") of the HCL cost report for their fiscal year ending in 2023; 36 percent had significant unexplained

costs reported and labeled as "Other" or "Miscellaneous" on their worksheet A-3 ("Tissue Typing Laboratory Costs"). Of those providers with significant unexplained costs reported, 30 percent had unexplained amounts that ranged from 19 percent to 33 percent of their total worksheet A-3 costs. Because we pay HCLs based on their reasonable costs, this lack of transparency is concerning and raises many questions about Medicare's payment accuracy on a reasonable cost basis.

In summary, in this proposed rule, we are proposing to reconcile IOPOs' and HCLs' organ acquisition costs for non-renal organs, following the same process we currently use to reconcile kidney acquisition costs, and to require the contractor to establish, adjust, if necessary, and disseminate the non-renal interim rates, using the same process followed for kidney interim rates. We are proposing a 1-year delay to provide time for us to update the IOPO and HCL cost report, and to provide time for IOPOs and HCLs to prepare for increased reporting of non-renal costs and revenue on their MCRs and greater contractor oversight of their non-renal SACs and HCL testing rates, with an effective date for cost reporting periods beginning on or after October 1, 2027. We believe these proposals, if finalized, will protect the Medicare Trust fund, reduce inappropriate spending, increase compliance with our reasonable cost principles, and protect IOPOs and HCLs from certain financial losses while continuing to support the transplant ecosystem.

## 2. Reasonable Cost Payment Policies

### a. Background

Medicare is often required, under section 1814(b) of the Act (for services covered under Part A) and under section 1833(a)(2) of the Act (for services covered under Part B), to pay for services furnished by providers on the basis of reasonable costs as defined in section 1861(v) of the Act, or the provider's customary charges for those services, if lower. Medicare reasonable costs are determined based on the provisions of section 1861(v) of the Act, and existing regulations under 42 CFR part 413. Medicare payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries.<sup>508</sup> Medicare's reasonable cost principles are also set forth in the CMS Pub. 15-1 (herein referred to as PRM-1).<sup>509</sup>

Under Medicare's reasonable cost reimbursement principles, Medicare reimburses providers for actual costs incurred for Medicare-related items and services, excluding unnecessary costs, in the efficient delivery of needed health services. The Medicare "reasonable cost" statute at section 1861(v) of the Act allows the Secretary to develop methods for measuring reimbursable costs such that the necessary costs of efficiently delivering covered services to Medicare beneficiaries will not be borne by non-Medicare beneficiaries, and the costs with respect to individuals who are not Medicare beneficiaries will not be borne by Medicare.

Some providers are reimbursed for all or some of their services on a reasonable cost basis such as critical access hospitals (CAHs) reimbursed at 101 percent of their reasonable costs; CAH swing-bed skilled nursing facilities (SNFs) reimbursed at 101 percent of their reasonable costs; rural health clinics (RHCs) reimbursed under the all-inclusive rate up to their payment limit; OPOs and HCLs reimbursed based on their reasonable cost for organ acquisition and tissue typing services; TEFRA hospitals (that is, children's hospitals, cancer hospitals, long term care hospitals classified as extended neoplastic disease care hospitals, and hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) reimbursed for their reasonable costs up to the TEFRA limit.

In general, Medicare makes interim payments to providers through claims processing and additionally, for any pass-through costs such as organ acquisition or nursing and allied health cost, based on estimated costs or predetermined rates. These payments are typically made on a biweekly basis throughout the year, ensuring a steady cash flow to providers until final cost determinations are made. After the cost reporting period ends, providers submit an MCR documenting their actual allowable costs. The contractor reviews the provider's cost report and calculates a settlement by comparing total interim payments made to the provider during the year with the provider's actual allowable reasonable costs as determined from the provider's cost report. It is this process by which Medicare determines a provider's reasonable costs. If interim payments exceed the provider's actual allowable reasonable costs, the provider must pay Medicare for the overpayment. If actual

<sup>507</sup> <https://oig.hhs.gov/reports/all/2018/national-institute-of-transplantation-an-independent-histocompatibility-laboratory-did-not-fully-comply-with-medicare-cost-reporting-requirements/>.

<sup>508</sup> Section 1861(v)(1)(A) of the Act; 42 CFR 413.9

<sup>509</sup> PRM-1, chapters 21 and 23. CMS Pub. 15-1 can be found at [https://www.cms.gov/Regulations-](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929)

[and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929).

allowable costs exceeded interim payments, Medicare pays the provider the additional amount owed.

#### b. Reasonable Cost Proposals

Section 1102 of the Act authorizes the Secretary to publish rules and regulations necessary for the efficient administration of the functions with which the Secretary is charged under the Act. Section 1871(a) of the Act also authorizes the Secretary to prescribe such regulations as may be necessary to carry out the administration of the Medicare Program. Additionally, under section 1861(v)(1)(A) of the Act, the Secretary has authority to determine reasonable costs of providing patient care to Medicare beneficiaries. In this proposed rule, we clarify existing policy and propose to codify certain longstanding Medicare reasonable cost reimbursement policies as well as to change certain other Medicare reasonable cost reimbursement policies.

In addition to the Medicare “reasonable cost” statute at section 1861(v) of the Act, part 413 of the regulations establishes Medicare’s principles of reasonable cost reimbursement. Under 42 CFR 413.1(a)(2), these regulations in part 413 govern Medicare payment for services provided to beneficiaries by the following provider types: hospitals, CAHs, rural emergency hospitals (REHs), skilled nursing facilities (SNFs), home health agencies (HHAs), ESRD facilities, OPOs, and HCLs.

Section 413.1(a)(2)(v) identifies OPOs as a provider type to which part 413 of the regulations apply, making them expressly subject to Medicare’s reasonable cost principles, including 42 CFR 413.9 regarding costs related to patient care. We find it necessary to restate this because OPOs have asserted in certain administrative appeals that reasonable cost principles and rules do not apply to them because they do not provide direct patient care. OPOs provide services directly related to patient care by procuring, perfusing, and transporting organs for transplantation into all organ recipients, including Medicare beneficiaries. An OPO must enter into an agreement with CMS, if it seeks payment under Medicare for organ procurement costs. An OPO incurs organ procurement costs for providing THs with organs for transplantation and for which the TH pays the OPO. When a Medicare beneficiary receives an organ transplant, the TH bills Medicare for the transplant and organ acquisition costs. As such, an OPO’s organ acquisition costs that are paid by the TH and passed on to Medicare clearly arise under the

Medicare statute under section 1861(v) and are governed by the statutory requirements and implementing regulations. As previously stated in section X.D.2. of this proposed rule, Public Law 95–292 required that the amounts of payments to OPOs and HCLs made under title XVIII for procuring organs must not exceed the costs incurred by OPOs and HCLs and must be determined in accordance with section 1861(v) of the Act. Accordingly, OPOs are subject to Medicare’s reasonable cost principles, the regulations in part 413, and the reasonable cost payment proposals in this proposed rule.

The Office of Inspector General (OIG) has conducted audits identifying instances in which providers including CAHs, transplant hospitals, and OPOs have claimed unallowable costs on their MCRs.<sup>510</sup> In these audits, the OIG has attributed the costs not meeting Medicare requirements to several factors including, the costs were not related to patient care, were not reasonable and necessary, were not adequately documented, and in some cases were unallowable entertainment costs. In its 2023 audit report, the OIG found that certain OPOs claimed unallowable costs because they misunderstood Medicare’s reasonable cost principles and provisions and recommended CMS update applicable Medicare requirements to clarify the allowability of certain overhead costs.<sup>511</sup> We believe the proposed provisions that follow will address key issues identified by the OIG regarding Medicare’s reasonable cost principles and provide clarity for all providers who seek reimbursement for services under Medicare’s reasonable cost provisions.

#### (1) Prudent Buyer Principles

Medicare’s longstanding prudent buyer principles are set forth in the PRM–1, chapter 21, section 2103, issued in 1975. Medicare’s prudent buyer principles also coincide with the principles set forth in the regulations at 42 CFR 413.9, Cost related to patient care. Implicit in the policy that payment

is determined based on costs that are reasonable is the expectation that the provider will seek to minimize its costs and that its actual costs will not exceed what a prudent and cost-conscious buyer would pay for a given item or service. The prudent and cost-conscious buyer not only refuses to pay more than the going price for an item or service but also seeks to economize by minimizing cost. This is especially so when the buyer is an institution or organization which makes bulk purchases and can, therefore, often gain discounts because of the size of its purchases. In addition, bulk purchase of items or services often gives the buyer leverage in bargaining with suppliers for other items or services. Another way to minimize cost is to obtain free replacements or reduced charges under warranties for medical devices. Any alert and cost-conscious buyer seeks such advantages, and it is expected that Medicare providers of services will also seek them. If costs are determined to exceed the level that prudent buyers incur, the excess costs are not allowable and not reimbursable under Medicare in the absence of clear evidence that the higher costs were unavoidable.

The PRM–1, chapter 21, section 2103 sets forth the following examples of the application of the prudent buyer principle where costs are not reimbursable because the prudent buyer principle has not been applied by the provider:

- Provider A consistently purchases supplies from supplier R and makes no effort to obtain the most advantageous price for its supplies. Supplier W sells identical or equivalent supplies at a lower cost and is also convenient to A. Unless the provider can clearly justify its practice of purchasing supplies from R rather than W, any excess of R’s charges over W’s charges is excluded from the provider’s costs.

- Supplier L supplies drugs to skilled nursing facility B and rents space from B to store the drugs to be used there. The rental paid by L to B for the space would generally constitute an indirect discount on the cost of drugs and must be reflected as a reduction of the cost of drugs supplied.

- Dr. C, a hospital-based radiologist, purchases radiology equipment which he then leases to the provider where he is a staff member. Costs to the provider in this case are higher than if the equipment had been leased through competitive bidding from an outside source. The Medicare contractor reimburses the provider only for those costs which a prudent and cost-conscious buyer would pay. Therefore, those costs which the provider pays for

<sup>510</sup> <https://oig.hhs.gov/oas/reports/region9/90800033.pdf>; <https://oig.hhs.gov/oas/reports/region9/90900087.pdf>; <https://oig.hhs.gov/oas/reports/region9/90500034A.pdf>; <https://oig.hhs.gov/reports/all/2011/review-of-select-medicare-conditions-of-participation-and-costs-claimed-at-richards-memorial-hospital-from-october-1-2004-through-september-30-2007/>; <https://oig.hhs.gov/oas/reports/region9/91102039.pdf>; <https://oig.hhs.gov/reports/all/2023/medicare-paid-independent-organ-procurement-organizations-over-half-a-million-dollars-for-professional-and-public-education-overhead-costs-that-did-not-meet-medicare-requirements/>.

<sup>511</sup> <https://oig.hhs.gov/documents/audit/9634/A-09-21-03020-Complete%20Report.pdf>.

the equipment leased from the staff radiologist which are in excess of costs for equivalent equipment obtained through competitive bidding are denied.

- Provider B purchases cardiac pacemakers or their components for use in replacing malfunctioning or obsolete equipment, without asking the supplier/manufacturer for full or partial credits or payments available under the terms of the warranty covering the replaced equipment. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment supplied.

Providers may incur costs that are not allowable under Medicare when they fail to apply the prudent buyer principle. Other examples where the prudent buyer principle has not been applied by the provider include, but are not limited to, fees paid to consultants, attorneys, or other professionals that are excessive compared to market rates or for services not directly related to patient care; equipment purchases that are more expensive or sophisticated than necessary for the provider's patient population; and costs for items that are not necessary for patient care or that represent luxury items may be disallowed.

The application of the prudent buyer principle is set forth in PRM 15–1, chapter 21, section 2103 and includes the following examples of methods that contractors<sup>512</sup> may employ for detecting and investigating situations in which costs seem excessive: comparing the prices paid by providers to the prices paid for similar items or services by comparable purchasers, spot-checking, and querying providers about indirect, as well as direct, discounts. We note that in addition to these examples contractors may employ other methods for determining which costs seem excessive, including but not limited to: use of IRS Form 990 in comparing reasonableness of executive and employee compensation with those at comparable institutions, use of federal per diem rates in determining the reasonableness of accommodations or meeting spaces for conferences and seminars for patient-care related activities and use of the provider's own records in determining whether costs of certain activities are reasonable and necessary. The geographic location of the provider should also be considered as rates may vary across regions.

We believe the use of IRS Form 990 is appropriate to compare compensation because the information provided is widely recognized in the industry, standardized and publicly available.

Additionally, we believe the use of Federal per diem rates are an appropriate method of comparison because they reflect industry norms and are established based on extensive data collection and analysis, account for geographic variations and are transparent. We also note these methods align with Medicare's reasonable cost regulation under 42 CFR 413.9(c) which provides that actual costs may vary among providers, however, costs must not be substantially out of line with similar institutions in the same area and of comparable size, scope, utilization and other relevant factors. Amounts not related to patient care, or flowing from the provision of luxury items or services are not reimbursable under the program and are not allowable costs.

The PRM–1, chapter 21, section 2103 also provides where a group of institutions has a joint purchasing arrangement which seems to result in participating members getting lower prices because of the advantages gained from bulk purchasing, any potentially eligible providers in the area which do not participate in the group may be called upon to justify any higher prices paid. Also, the manual provides that when most of the costs of a service are reimbursed by Medicare (for example, for a home health agency which treats only Medicare beneficiaries), examine the costs with particular care. In those cases where a contractor notes that a provider pays more than the going price for a supply or service or does not try to realize savings available under warranties for medical devices or other items, in the absence of clear justification for the premium, the contractor excludes excess costs in determining allowable costs under Medicare.

In this proposed rule, we are proposing to codify a definition of the prudent buyer in accordance with the principle set forth in PRM–1, section 2103 and that reflects similar terminology used across financial, legal, and insurance fields as well as propose to codify the application of the prudent buyer principle currently set forth in PRM–1, section 2103. Specifically, in this proposed rule, we are proposing to revise § 413.9(b) to add paragraph (b)(3) to specify that the prudent buyer is a person, provider type or entity that purchases items or property with caution, good judgment, and a sensible approach, aiming to make a sound, informed decision that minimizes risk and avoids unnecessary financial loss. This person, provider type or entity thoughtfully evaluates the condition, legal, and financial aspects of a purchase, much like a reasonably

prudent person would in a similar situation.

In this proposed rule, we are also proposing to revise § 413.9(c) to add paragraph (c)(4) to codify the application of the prudent buyer principle to providers to specify that providers are expected to economize by not paying more than the going price for an item or service and seeking to minimize their costs, so that their actual costs will not exceed what a prudent and cost-conscious buyer would pay for a given item or service. If costs are determined to exceed the level that prudent buyers incur, the excess costs are not reimbursable in the absence of clear evidence that the higher costs were unavoidable.

#### (2) Entertainment and OPOs Public Education and Outreach for Organ Donation Awareness

Under section 1861(v)(8) of the Act, costs for entertainment, including tickets to sporting and other entertainment events, must not be included in a provider's costs for Medicare reimbursement purposes because they are not reasonable costs related to patient care. The PRM–1, chapter 21, section 2105.8 sets forth that “Costs incurred by providers for entertainment, including tickets to sporting or other events, alcoholic beverages, golf outings, ski trips, cruises, professional musicians or other entertainers, are not allowable.” Additionally, PRM–1, chapter 21, section 2102.3 provides that, “Costs not related to patient care are costs which are not appropriate or necessary and proper in developing and maintaining the operation of patient care facilities and activities. Costs which are not necessary include costs which usually are not common or accepted occurrences in the field of the provider's activity. Such costs are not allowable in computing reimbursable costs and include, for example: cost of meals sold to visitors; cost of drugs sold to other than patients; cost of operation of a gift shop; cost of alcoholic beverages furnished to employees or to others regardless of how or where furnished, such as cost of alcoholic beverages furnished at a provider picnic or furnished as a fringe benefit; cost of gifts or donations; cost of entertainment, including tickets to sporting and other entertainment events; cost of personal use of motor vehicles; cost of fines or penalties resulting from violations of Federal, State, or local laws; cost of educational expenses for spouses or other dependents of providers of services, their employees or contractors, if they are not active employees of the

<sup>512</sup> (79 FR 49854 at 50199 on August 22, 2014).

provider or contractor; cost of meals served to executives that exceed the cost of meals served to ordinary employees due to the use of separate executive dining facilities (capital and capital-related costs), duplicative or additional food service staff (chef, waiters/waitresses, etc.), upgraded or gourmet menus, etc.; and cost of travel incurred in connection with non-patient care related purposes.”

Despite this instruction, some providers continue to include inappropriate expenses for entertainment and sporting activities on their MCRs and CMS’s disallowance of these costs often results in appeals. For example, some OPOs are reporting costs on their OPO/HCL MCR, Form CMS–216–94, (OMB control number 0938–0102), (hereinafter referred to as OPO/HCL MCR), for items such as the sponsorship of professional sports teams, sponsorship of race car drivers at nationally viewed racing events, sponsorship of floats at nationally viewed parades, and costs for musical entertainment and performers at these events. Some of these sponsorships have included items such as, full season tickets to professional basketball games, autographed items, tickets to racing events, entrance to hospitality suites, sponsorship of Indy Car teams and dirt track race cars, rides in an Indy Car, pit lane and garage tours and driver appearances at off-track events. These types of costs are not reasonable costs related to patient care and therefore, are unallowable under Medicare’s reasonable cost principles.

Under section 371(b)(3)(B) of the PHSA, OPOs are responsible to “conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,” and “assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.” We have recognized the importance of OPOs implementing public education activities to increase organ donation awareness and increase the donor registration. (In the context of OPOs’ public education activities, we note that the terms public education, public outreach, or public awareness have the same meaning and may be used interchangeably.) We have historically afforded OPOs the flexibility to allocate educational resources based on their individual donation service area (DSA) needs.<sup>513</sup> Medicare currently recognizes

the costs incurred by OPOs for public education regarding organ donation awareness as allowable costs if they are reasonable and necessary and related to patient care. The current OPO/HCL MCR instructions set forth that public education costs are expenses associated with organizing awareness programs designed to inform the “general public” of the need for organs and organ transplant services.<sup>514</sup> OPOs include professional and public education costs as OPO overhead costs on their OPO/HCL MCR, and Medicare shares in these costs.

Some OPOs have asserted that their engagement in entertainment and sporting events, such as sponsoring parade floats, purchasing tickets to sporting events, engaging or purchasing tickets for musical entertainers and performers, lodging, food and beverages, and sponsoring professional race car driving events, are types of public education costs that serve to reach large audiences to educate potential donors regarding the benefits of organ donation, and thus recruit candidates for organ donor registries. OPOs’ sponsorship costs for these entertainment and sporting events, declared by OPOs to be public education events, vary depending upon the event type and additional items the OPO can select for the sponsorship level that may increase the cost to the OPO.

One report indicated that costs to build a float in the Rose Bowl Parade may be in the vicinity of \$125,000 to \$500,000 per parade event.<sup>515</sup> In one audit, the OIG found that an OPO incurred \$327,278 of costs related to the 2006 Rose Parade and Rose Bowl, and reported \$153,513 costs as public education overhead costs on its OPO/HCL MCR related to the Rose Parade and Rose Bowl.<sup>516</sup> The OIG categorized these costs as unallowable because they were incurred for entertainment and sporting events, in accordance with PRM–1, chapter 21, sections 2102.3 and

and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an area and that meets the standards of 42 CFR 486.302 subpart G. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act. (42 CFR 486.302).

<sup>514</sup> PRM–2, chapter 33, section 3304, Worksheet A, line 11.

<sup>515</sup> <https://spectrumnews1.com/ca/southern-california/news/2021/07/09/parade-float-builder-faces-steep-costs-as-rose-parade-preparations-begin#:~:text=Estes%20said%20each%20float%20takes,ranges%20from%20%24125%20C000%20to%20%24500%20C000.>

<sup>516</sup> <https://oig.hhs.gov/oas/reports/region9/90800033.pdf>.

2105.8.<sup>517</sup> The unallowable costs identified by OIG included costs for: float design, lodging, receptions, banquets and use of hotel ballroom, chartered buses, shuttles and limousines for parade day, media expenses, such as audiovisual equipment, photography and television coverage, musical performances, and other costs such as food and beverage, public storage and flowers.<sup>518</sup> We have also seen some OPOs reporting sponsorship costs for a race car driver, at an Indy Car event in the hundreds of thousands of dollars per sponsorship. These types of OPO-sponsored entertainment and sporting events far exceed what a cost-conscious buyer, in this case an OPO, should spend for providing targeted public education regarding organ donation within its DSA. The result is OPOs including costs on their OPO/HCL MCR that are in excess than those generally considered necessary for the provision of needed health services, and therefore, unallowable under Medicare’s reasonable cost principles and § 413.9. Cost related to patient care. While these entertainment and sporting events may attract wide viewership and occur within the OPO’s DSA, such factors do not constitute targeted public education initiatives, measure attendees or focused educational conversations, or demonstrate measurable successes and increases in donor registration.

We are aware of several OPOs conducting successful, cost-effective public education events within their DSAs while observing Medicare’s reasonable cost principles and fulfilling their objectives of increasing donor registrations. These public education events have successfully increased the number of registered donors and effectively reached underrepresented groups within their DSA. For example, some OPOs have engaged with local high schools and colleges, Health Occupational Student Associations, and participated in local multicultural outreach events and set up booths at minor league baseball games and events within their communities and demonstrated successful organ donor registration at these engagements.

We believe for OPOs’ public education costs to be allowable under Medicare, the costs incurred must be for direct engagement in public outreach and education events for efforts that are more direct and systematic to target populations within their DSAs and where one-on-one activity and conversations can take place to educate and register individuals for organ

<sup>517</sup> Id.

<sup>518</sup> Id.

<sup>513</sup> 71 FR 31027, May 31, 2006. CMS defines DSA to mean a geographical area of sufficient size to ensure maximum effectiveness in the procurement

donation. Specifically, we believe allowable OPO public education costs are for an OPO's community-based and locally focused efforts and effects, that include opportunities to register donors and track the number of registrations obtained during each effort. The OPO staff should be available to answer questions directly about the organ donation process and may provide modest token items and educational materials to individuals to support organ donation awareness (for example, pens, awareness bracelets, buttons, stickers, cups, or electronic and print materials that include the OPO's website address, QR codes linking to donor registration platforms, or information on upcoming community-based organ donation awareness events).

We believe that allowable costs under Medicare for OPO public education initiatives include costs that directly support organ donation and align with Medicare's reasonable cost principles. Examples would include OPOs' participation and engagement in settings that can facilitate direct conversations with individuals regarding organ donation such as, setting up booths at local farmer's markets, health fairs, high school or local college sporting events, partnering with community organizations, faith-based groups, schools and health care facilities, participating in local multicultural festivals, providing education at driver's education programs and at local Department of Motor Vehicles (DMV) and Department of Natural Resources so that individuals can register to become an organ donor while obtaining a driver's license or fishing license.

The 2025 National Survey of Organ Donation Attitudes and Practices: Report of Findings<sup>519</sup> reported that 89.3 percent of people who registered to be organ donors did so at a state DMV or similar State motor vehicle administration office. According to the report, other methods of donor registration include 12.4 percent who had registered through donor drives, 10.3 percent through mobile apps, 11.6 percent through a website, 9.6 percent through the U.S. military and 11.8 percent through some other way. The report also noted that those under age 50 as well as Black, Asian, Hispanic, and other/multiple races were more likely to register through a donor drive, mobile app, or website. Although most organ donors are registered via the DMV, there remain underrepresented groups within OPOs' DSAs whose

registration rates could benefit from targeted community-based outreach.<sup>520</sup>

We do not believe that OPOs should incur costs and seek reimbursement from Medicare for engaging in national organ donor awareness campaigns. Health Resources and Services Administration (HRSA) is authorized, on behalf of the Secretary of Health and Human Services, to develop a public awareness program that partners with existing national campaigns to inform the public about organ donation.<sup>521</sup> In the past, HRSA received Federal funding for public awareness of organ donation programs.<sup>522</sup> Additionally, some of HRSA's past public outreach activities have consisted of developing and disseminating consumer-focused materials, including downloadable posters; fact sheets and brochures; radio, print, and television Public Service Announcements; educational videos; paid media advertisements; radio media tours; billboards, wall graphics at major airports, and social media messages.<sup>523</sup> HRSA currently manages ongoing resources such as *Organdonor.gov*, the U.S. government's central resource for comprehensive, trusted information on organ, eye, and tissue donation and uses this website to educate the public, encourage donor registration, and provide access to a library of outreach and educational materials.<sup>524</sup> OPOs are permitted to use HRSA's outreach materials library to access free educational resources for organ donation awareness activities. We believe utilizing these materials may represent more cost-effective methods of increasing awareness than sponsoring national entertainment-oriented events that incur substantial expenditures. Considering the past Federal expenditures and ongoing efforts from HRSA for national public awareness, it seems that an individual OPO's request for reimbursement from Medicare for national-level outreach activities of a similar nature may be duplicative of HRSA's efforts for national awareness purposes.

We are committed to carefully and responsibly stewarding the tax dollars in the Medicare Trust Fund, and do not believe that providers should be claiming unreasonable, non-allowable, or non-reimbursable costs for

reimbursement under Medicare on the Medicare cost report. Therefore, in this proposed rule, we are proposing to codify existing policy set forth in PRM–1, chapter 21, sections 2102.3 and 2105.8, while also providing greater specificity regarding unallowable entertainment costs for providers, including to specify that such unallowable costs include sponsorship of sporting events, teams or athletes, including race car drivers or motorsports activities, retreats held at spas or luxury resorts, spa services or treatments, and recreational excursions. In this proposed rule, we are also proposing to codify the current policy set forth in the OPO/HCL MCR;<sup>525</sup> in doing so, we also propose to provide greater specificity regarding allowable public education costs for OPOs.

Specifically, we are proposing to add § 413.5(c)(10) to specify that costs incurred by providers for entertainment, including costs associated with entertainment activities, or that are entertainment in nature, are not allowable costs. We are proposing to add § 413.5(c)(10)(i) to specify that—(1) paragraph (c)(10) includes costs that OPOs incur to engage in public education to increase awareness of organ donation and increase donor registration; and (2) non-allowable entertainment costs include, but are not limited to the following:

- Tickets, admission fees, or entry to sporting or other events, including national or professional sporting events.
- Sponsorship of sporting events, teams or athletes, including race car drivers or motorsports activities.
- Sponsorship of floats in national parades.
- Concert, theater, or performing arts events, professional musicians or other entertainers.
- Wine tours or alcoholic beverages.
- Retreats held at spas or luxury resorts, spa services or treatments.
- Golf outings, ski trips, cruises and similar recreational excursions.

In this proposed rule, we are also proposing to add § 413.5(c)(11) to specify that costs incurred by OPOs to engage in public education within its donation service area to increase awareness of organ donation and increase donor registration are allowable if they are reasonable and do not violate § 413.5(c)(10). We are also proposing to amend § 413.402(a) and (d)(2)(v) to cross-reference the policy set forth in § 413.5(c)(11) regarding OPOs' public education costs. Additionally, in this proposed rule, we are proposing to

<sup>520</sup> <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#>.

<sup>521</sup> 42 U.S.C. 274f–1(a).

<sup>522</sup> <https://www.congress.gov/bills/108th-congress/house-bill/3926/text/statute?format=txt>.

<sup>523</sup> [https://www.govinfo.gov/content/pkg/CMR-HE20\\_9000-00192981/pdf/CMR-HE20\\_9000-00192981.pdf](https://www.govinfo.gov/content/pkg/CMR-HE20_9000-00192981/pdf/CMR-HE20_9000-00192981.pdf).

<sup>524</sup> <https://www.organdonor.gov/professionals/outreach-materials>.

<sup>519</sup> 2025 National Survey of Organ Donation Attitudes and Practices Report of Findings..

<sup>525</sup> PRM–2, chapter 33, section 3304, Worksheet A, line 11.



codify our longstanding policy in PRM–1 chapter 21, section 2102.3 regarding certain unallowable costs incurred by providers for drugs sold to other than patients, fines and penalties, and expenses associated with operating a gift shop. Specifically, we are proposing to add § 413.5(c)(17) to specify that costs incurred by providers for drugs sold to other than patients are not related to patient care and are not allowable costs. We are proposing to add § 413.5(c)(18) to specify that costs incurred by providers for fines or penalties resulting from Federal, State or local laws are not allowable costs. Lastly, we are proposing to add § 413.5(c)(19) to specify that costs incurred by providers for operation of a gift shop are not allowable costs.

### (3) Activities for Employees and Non-employees of the Provider

The PRM–1, chapter 21, section 2105.8 sets forth that “Costs incurred by providers for entertainment, including tickets to sporting or other events, alcoholic beverages, golf outings, ski trips, cruises, professional musicians or other entertainers, are not allowable.” We continue to believe that these costs are appropriately excluded from allowable costs. However, PRM–1, chapter 21, section 2105.8 also states that “Costs incurred by providers for purposes of employee morale, specifically, for an annual employee picnic, an annual Christmas or holiday party, an annual employee award ceremony or for sponsorship of employee athletic programs (for example, bowling, softball, basketball teams, etc.), are allowable to the extent that they are reasonable.” After further consideration, we believe that costs incurred by providers for events for their employees and non-employees such as employee picnics, parties, award ceremonies or for the sponsorship of employee athletic programs should not be allowable costs under Medicare, as they are not costs a provider incurs to provide patient care. While we understand the significance of employee events provided by providers for their employees’ morale, we believe that costs associated with employee and non-employee entertainment do not coincide with Medicare’s reasonable cost principles and are not costs related to patient care as required under 42 CFR 413.9.

There are many cost-effective methods for improving employee morale that do not require entertainment expenses. Flexible work schedules, wellness programs, recognition for achievements, and creating a positive workplace culture are

just a few examples of ways to support employees without impacting healthcare resources. (These items are separate from a provider’s cost of fringe benefits provided to employees under the PRM–1, chapter 21, section 2144.4 that may be recognized as a provider’s costs for Medicare reimbursement purposes. Employee fringe benefits that are part of a formal written policy and considered reasonable compensation (for example, health insurance, retirement plans) are generally allowable costs under Medicare.)

Therefore, in this proposed rule we are proposing to change the current policy provided in PRM–1, chapter 21, section 2105.8 to disallow costs incurred by providers for employees or non-employees or anyone for entertainment expenses for employee entertainment activities and employee morale, including but not limited to those set forth in PRM–1, chapter 21, section 2105.8, because they are not related to providing patient care. Specifically, we are proposing to add 42 CFR 413.5(c)(12) to specify that costs incurred by providers for anyone for purposes of employee and non-employee entertainment activities and employee morale, which include, but are not limited to, picnics, parties, performers, entertainment, award ceremonies, or the sponsorship of scholarships or athletic programs are not allowable costs.

### (4) Alcoholic Beverages

The PRM–1, chapter 21, section 2105.8 sets forth that costs incurred by providers for alcoholic beverages are not allowable. Additionally, PRM–1, chapter 21, section 2102.3 sets forth that a provider’s “cost of alcoholic beverages furnished to employees or to others regardless of how or where furnished, such as cost of alcoholic beverages furnished at a provider picnic or furnished as a fringe benefit, are not allowable in computing reimbursable costs.” OIG audits have found, and we have seen instances where some providers have included costs for furnishing alcohol in their MCRs, despite these prohibitions outlined in the PRM–1.<sup>526</sup> A provider’s costs to furnish alcohol to anyone are not related to patient care and are not appropriate, necessary, or proper in developing and maintaining the operation of patient care facilities and activities. Therefore, in this proposed rule, we are proposing to codify these longstanding provisions

into the regulations by adding § 413.5(c)(13) to specify that costs incurred by providers to furnish alcoholic beverages to anyone are not allowable costs.

### (5) Professional Education and Travel

#### (a) Costs for OPO Professional Education

Regarding allowable professional education costs for OPOs, under section 371(b)(3)(B) of the PHSA, OPOs are responsible to “conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,” and “assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.” Medicare has recognized the costs incurred by OPOs’ for providing professional education for increasing organ donation awareness and acquiring organs for transplantation as allowable costs, if such costs are reasonable, necessary and related to patient care. OPOs include professional education costs as OPO overhead costs on the OPO/HCL MCR, and Medicare shares in these costs. The current guidance regarding allowable professional education costs is set forth in the OPO/HCL MCR and includes, “costs associated with the education of donor hospital personnel and physicians, including the expenses of meetings, seminars, slide shows, and presentations.”<sup>527</sup>

In 2023, the OIG reviewed OPOs’ expenses and found that Medicare paid for costs incurred for professional and public education activities that did not meet Medicare requirements.<sup>528</sup> The OIG recommended CMS update the applicable requirements to clarify what types of professional and public education costs are unallowable.<sup>529</sup> We note that we discuss public education costs in section X.D.2.b.(2) of the preamble of this proposed rule. In this proposed rule, we are establishing in regulation that the types of professional education provided by OPOs to the clinical staff of hospitals should be focused on organ donation to acquire all useable organs from potential donors in accordance with section 371(b)(3)(B) of the PHSA.

In response to comment in the FY 2022 IPPS/LTCH PPS final rule with comment period, we stated that costs of

<sup>527</sup> PRM–2, chapter 33, section 3304, Worksheet A, line 10.

<sup>526</sup> <https://oig.hhs.gov/oas/reports/region9/90800033.pdf>; <https://oig.hhs.gov/oas/reports/region9/90900087.pdf>; <https://oig.hhs.gov/documents/audit/9634/A-09-21-03020-Complete%20Report.pdf>.

<sup>528</sup> <https://oig.hhs.gov/reports/all/2023/medicare-paid-independent-organ-procurement-organizations-over-half-a-million-dollars-for-professional-and-public-education-overhead-costs-that-did-not-meet-medicare-requirements/>.

<sup>529</sup> *Id.*



an OPO-sponsored seminar that does not provide continuing education credits, regardless of whether the seminar is provided to the OPO staff, may be an allowable cost if it relates to patient care and meets the requirements at 42 CFR 413.9. (see 86 FR 73476). In this proposed rule we are providing additional specificity regarding both the nature of the education offered at OPO-sponsored seminars and the intended audience for such seminars as referenced in our previous statement. The OPO-sponsored seminars may include meetings, presentations, and other professional education activities that do not offer continuing education credits, provided to clinical staff such as OPO personnel, donor hospital staff, and physicians and the content is directly related to organ donation and the acquisition of all available organs for transplantation. These costs must meet Medicare's reasonable cost principles and be related to patient care as set forth at § 413.9. Therefore, in accordance with OIG's recommendations regarding clarification of allowable professional education costs, in this proposed rule, we are proposing to codify existing policy, with certain modifications to provide greater specificity, set forth in OPO/HCL MCR instructions and requirements under section 371(b)(3)(B) of the PHSA regarding OPO professional education costs.

In this proposed rule, we are proposing to add new paragraph (c)(14)(i) to specify that the costs incurred by OPOs for professional education such as meetings, seminars, and presentations on organ donation to acquire all useable organs from potential donors, where continuing education credits are not given and where the attendee is clinical staff such as OPO staff, donor hospital staff, and physicians, are allowable costs.

Additionally, in response to a comment in the FY 2022 IPPS Final Rule with comment period, (86 FR 73476), we stated, the reasonable cost of an OPO-sponsored seminar that provides continuing education credits, may be an allowable administrative and general cost limited to the OPO staff (as described at § 486.326(b)) if the seminar is related to patient care and meets the requirements at § 413.9. In this proposed rule, we are proposing to codify the existing policy regarding allowable costs of OPO-sponsored seminars where continuing education credits are given to the OPO staff. Specifically, we are proposing to add new paragraph (c)(14)(ii) to specify, the costs for OPO-sponsored seminars

where continuing education credits are given and where the attendee is on the OPO staff are allowable costs to the extent that they are patient care related, reasonable and necessary and we are also proposing to add new paragraph (c)(14)(iii) in accordance with existing requirements under § 413.402(d)(2)(v) that costs incurred by OPOs for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO staff are not allowable costs. Lastly, we are proposing to amend sections 413.402(a) and (d)(2)(v) to cross-reference the policy set forth in § 413.5(c)(14)(iii) regarding OPOs professional education costs.

#### (b) Costs for Education and Travel

The PRM-1, chapter 21 sets forth that the costs of staff training and education are allowable, provided they are reasonable and related to patient care. Specifically, the PRM-1, chapter 21 section 2128 states that orientation and on-the-job training costs are recognized as normal operating expenses and are therefore allowable. Such training is typically conducted within the provider's own setting; however, if outside instruction is required, those costs are also considered allowable. Additionally, the PRM-1, chapter 21, section 2144.6 provides that the cost of items provided to the employee for the convenience of the provider, such as the cost of provider-paid educational courses, uniforms, and operating day care centers for the children of employees are not classified as fringe benefits and may be included in a provider's allowable cost to the extent they are reasonable and related to patient care. The PRM-1, chapter 21, section 2162.7 D. also specifies that providers are required to maintain continuous safety initiatives and professional and employee training programs aimed at reducing the severity of incidents related to malpractice, comprehensive general liability, and workers' compensation incidents.

Regarding travel costs, the PRM-1, chapter 21, section 2105.6 sets forth that costs incurred by providers in conjunction with employee travel are generally allowable to the extent that they are patient care related and reasonable. However, travel costs incurred in conjunction with non-patient care related employee travel are not allowable. Foreign travel costs are allowable only where the provider can clearly substantiate the reasonableness and patient care relatedness of the travel costs to the satisfaction of the Medicare contractor.

When providers incur costs for their employees or staff to travel to professional education activities, these costs must be for activities related to patient care, reasonable and necessary in accordance with Medicare's reasonable cost principles. In this proposed rule, we are clarifying that overnight travel costs incurred by a provider on behalf of its employees or staff for activities related to patient care to attend a professional education course, meeting, or similar event should be considered allowable when the event is located more than 50 miles away from the employee's workplace and requires more than 8 hours of attendance. We believe this clarification reflects standard business practices. An 8-hour workday is widely recognized across industries, and many federal agencies define local travel as occurring within a 50-mile radius of an employee's official worksite.<sup>530</sup> Additionally, we believe providers are expected to minimize travel-related costs to professional education activities by selecting economy or coach class accommodations.

Additionally, section 1861(v)(8)(iii) of the Act and PRM-1, chapter 21, section 2105.9 also provides that the costs incurred by providers related to employee personal use of provider vehicles are not allowable costs. In one OIG audit, the OIG found that a provider reported costs for chartered buses, shuttles, and limousines for Rose Bowl float judging and parade day on its Medicare cost report that were unallowable because they were entertainment focused and not related to patient care.<sup>531</sup>

Under section 1861(v)(8)(v) of the Act, education expenses for spouses or other dependents of providers of services, their employees or contractors are unrelated to patient care and not allowable. We note a 1998 PRRB decision permitted the provider's cost of an educational seminar that took place on a cruise ship as an allowable educational activity, *McCurry's Home*

<sup>530</sup> [https://www.irs.gov/irm/part1/irm\\_01-032-001#:~:text=\(11\)%201.32.,local%20long%20term%20taxable%20travel;https://www.gsa.gov/directives/files?file=2025-07%2FCCO50151%20OAS%205770.1B%20Local%20Travel%20Policy%20%28Clearance%29%20%281%29.pdf](https://www.irs.gov/irm/part1/irm_01-032-001#:~:text=(11)%201.32.,local%20long%20term%20taxable%20travel;https://www.gsa.gov/directives/files?file=2025-07%2FCCO50151%20OAS%205770.1B%20Local%20Travel%20Policy%20%28Clearance%29%20%281%29.pdf) <https://www.transportation.gov/media/1751#:~:text=Local%20Travel:%20DOT%20defines%20local%20travel%20as%20travel%20for%20official%20government%20business%20within%20a.>

<sup>531</sup> <https://oig.hhs.gov/oas/reports/region9/90800033.pdf>.

*Health, Inc. v. Blue Cross & Blue Shield Ass'n/Blue Cross & Blue Shield of Iowa*, (Decision 98–D38, 1998 WL 598425 (H.C.F.A. June 5, 1998)).<sup>532</sup> In *McCurry's Home Health, Inc.*, the Administrator reviewed and overturned the PRRB decision and declared that Medicare, as a prudent purchaser of health care services, was correct to question the reasonableness of the costs. The Administrator also declared that costs incurred by providers for cruises are not costs that are “common and accepted occurrences in the field of the provider’s activity” within the definition of necessary and proper costs under 42 CFR 413.9. Additionally, the Administrator said that the provider’s contention that there were no other seminars in its area or nearby that offered comparable educational information was not sufficient to make costs associated with a 7-day cruise to Alaska for employees based in Kansas City reimbursable, despite the 32 continuing education credits provided by the seminar. The Administrator declared that costs associated with the cruise other than the \$350 per attendee in actual costs of the seminar were unreasonable.

We agree that the costs of a cruise, regardless of whether continuing education credits are provided, are not common and accepted occurrences in the field of the provider’s activity, are not reasonable and necessary and are not patient care related. We believe that entertainment, travel and vacation type of expenses, are not related to patient care and are not appropriate or allowable as professional educational expenses. Such expenses are not necessary or proper in developing and maintaining the operation of patient care facilities and activities.

In this proposed rule, we are proposing to codify the existing policy in PRM–1, chapter 21, sections 2105.6, 2105.9, 2128, 2144.6, and 2162.7 D, with certain modifications to provide greater specificity regarding education and travel costs. Specifically, in this proposed rule we are proposing to add new 42 CFR 413.5(c)(15) to specify that costs incurred by providers:

- For employee travel are generally allowable to the extent that they are patient care related, reasonable and necessary. Costs for travel not related to patient care are not allowable costs.
- To conduct, or send its employees or staff to, patient care related professional education refresher

programs, seminars and workshops that increase the quality of patient care or operating efficiency of the provider, are generally allowable costs to the extent that they are patient care related, reasonable and necessary.

- For entertainment and vacation travel expenses such as travel on cruises or to resorts or spas, or transportation to entertainment or sporting events, are not allowable costs regardless of whether they are or are not incurred in connection with professional educational seminars or continuing education.

- Related to the personal use of provider vehicles are not allowable costs.

#### (6) Meals Provided to Employees and Non-Personnel

Medicare’s longstanding manual provisions regarding the allowability of a provider’s costs for meals for its employees/personnel and meals provided to those other than the personnel of the provider are provided in PRM–1, chapter 21, sections 2105.2, 2105.5, and 2145, and meals sold to visitors are provided in section 2102.3. These policies were established decades ago and we believe they require updating to ensure costs are reasonable and necessary and are incurred for patient care activities, in accordance with Medicare’s reasonable cost principles.

Section 2105.2 of PRM–1, chapter 21 states that the cost of meals for other than provider personnel is unallowable because it is not related to patient care. We have seen some OPOs assert in reimbursement appeals that meals provided to hospital staff during organ donation and management meetings constituted professional education overhead costs related to patient care and were therefore allowable. In 2023, the OIG reviewed certain OPOs’ overhead costs and found some costs for meals were attributable to non-OPO employees. In its review, the OIG sampled 20 professional and public education overhead costs (reported by eight OPOs), totaling \$4,637, and found instances where meals were provided to non-OPO employees, with Medicare payments of \$1,797.<sup>533</sup> OIG recommended that we clarify whether costs of meals provided to non-OPO employees were allowable.

Additionally, in response to comment in the FY 2022 IPPS/LTCH final rule with comment period (86 FR 73416), we

said that meals (excluding alcohol) provided to attendees of OPO-sponsored seminars (without continuing education credits) could be allowable administrative and general costs, provided the seminar related to patient care and met requirements under § 413.9 (86 FR 73476). However, upon further review, we believe the cost of meals at OPO-sponsored seminars is a benefit to the seminar attendees, rather than a direct cost necessary for patient care. In this proposed rule, we are proposing to change our previous position to better align with Medicare’s reasonable cost principles, 42 CFR 413.9 and section 2105.2 of PRM–1, which provides that the costs for meals provided to non-employees of the provider are unallowable costs.

In a PRRB decision, the Board allowed a portion of costs incurred by a provider for refreshments at a community health education event, *McCurry's Home Health, Inc. v. Blue Cross & Blue Shield Ass'n/Blue Cross & Blue Shield of Iowa* (Decision 98–D38, 1998 WL 598425 (H.C.F.A. June 5, 1998)).<sup>534</sup> Upon Administrator review of the PRRB decision, the Administrator declared that the provider’s costs for refreshments at the educational event were not reasonable costs related to the care of the provider’s own patients, citing the provisions of § 413.9. We believe that meals provided to anyone, regardless of whether they are or are not employees or staff of the provider, would represent personal expenses and therefore should not be considered allowable costs directly related to patient care services.

PRM–1, chapter 21, section 2105.5 provides that excess costs for executive or management employee meals—such as separate dining facilities, additional staff, or upgraded menus—are not allowable. However, PRM–1, chapter 21, section 2105.5 sets forth that unrecovered costs for executive or management meals served from common menus in shared employee dining facilities are allowable if otherwise reasonable. Under PRM–1, chapter 21, section 2145, providers may claim reasonable unrecovered costs for employee meals in two circumstances when meals: (1) qualify as a fringe benefit (see PRM–1, chapter 21, section 2144.4E) related to patient care; and (2) are provided solely for the provider’s benefit and related to patient care, as outlined in PRM–1, chapter 21, section 2102.2. For example, this includes meals served to personnel who must

<sup>532</sup> <https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Downloads/1998D038.pdf#:~:text=The%20Provider%20contents%20that%20the,administrative%20functions%20of%20the%20job.>

<sup>533</sup> <https://oig.hhs.gov/reports/all/2023/medicare-paid-independent-organ-procurement-organizations-over-half-a-million-dollars-for-professional-and-public-education-overhead-costs-that-did-not-meet-medicare-requirements/>.

<sup>534</sup> <https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Downloads/1998D038.pdf>.

remain on-call on the premises during mealtime to provide patient care, where the meal cost is not classified as a fringe benefit.

We believe the existing manual provisions under PRM–1, chapter 21, sections 2105.2, 2105.5 and 2145 should be revised to better align with Medicare's reasonable cost principles, including § 413.9. As noted, we believe that meals provided to employees or staff of the provider would generally be considered a personal benefit to staff rather than a direct cost necessary for patient care under Medicare and therefore should not be considered allowable costs. For the foregoing reasons, in this proposed rule, we are proposing to codify certain longstanding policy in PRM–1, chapter 21, section 2102.3 and revise the existing policy in sections PRM–1, chapter 21, sections 2105.2, 2105.5, and 2145.

Specifically, we are proposing to add § 413.5(c)(16) to specify that costs incurred by providers for meals sold to visitors and meals for their employees or staff (including executives and management) and non-personnel (including attending physicians) are not allowable costs. We are also proposing to specify that the costs of meals and refreshments provided to attendees at educational events, including attendees of OPO-sponsored seminars (with or without continuing education credits) are not allowable costs.

### 3. Clarification and Codification of Cost Allocation Principles

Medicare's reasonable cost reimbursement principles require correct allocation of such costs to arrive at equitable and proper payment for services to Medicare beneficiaries. Medicare regulations at 42 CFR 413.24 require that providers receiving payment on the basis of reimbursable cost provide adequate cost data based on their financial and statistical records which must be capable of verification by qualified auditors, and the cost data must be based on an approved method of cost finding.

Medicare's reasonable cost principles take into account both direct and indirect costs of providers of services. Direct costs are costs that are specifically identifiable and attributable to an individual patient, a particular cost center, or a department.<sup>535</sup> Examples of direct costs are salaries and wages of staff working exclusively in a specific department (for example, a nurse in the ICU), medical supplies used directly in patient care, medications administered to patients,

supplies used in specific departments (for example, the operating room or radiology department), CAR–T cell biologics administered to patients, and organs purchased from organ procurement organizations and transplant hospitals for transplant into patients. Indirect costs, on the other hand, are costs that are not chargeable based on actual usage and must be allocated on a basis of a statistical surrogate (for example, square feet, dollar value, FTEs, gross salaries, accumulated cost, and costed requisition). Examples of indirect costs are administration, rent, depreciation, utilities, housekeeping, maintenance, medical records, and employee benefits. Cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services furnished to patients by the allocation of direct costs and proration of indirect, or overhead, costs.

Departments within a provider are usually divided into two types: (1) those that produce patient care revenue (for example, routine services and radiology); and (2) those that do not directly generate patient care revenue but are utilized as a service by other departments (for example, administration, laundry and linen, housekeeping and dietary).<sup>536</sup> The two types of departments are commonly referred to as “revenue-producing cost centers” and “nonrevenue-producing cost centers.”<sup>537</sup> Cost finding employs the computation needed in determining the full costs of departments.

The Step-Down method of cost finding used by providers for cost reporting periods after December 31, 1971, recognizes that services rendered by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue-producing centers, as well as by the revenue-producing centers.<sup>538</sup> A provider's general service costs (that is, overhead costs) must be properly allocated to all centers which they serve, regardless of whether these centers produce revenue, to ensure costs for services to Medicare beneficiaries are correctly calculated.<sup>539</sup> This allocation process for Medicare cost reporting purposes is made through cost finding using a statistical basis that measures the benefit received by each cost center. The statistical basis must reflect the cause-and-effect relationship between the cost and the activities or

services receiving the allocation, that is, the benefit received by each cost center.<sup>540</sup> The statistical measure must demonstrate how costs incurred relate to the consumption of resources.<sup>541</sup>

The Medicare cost report's (MCR's) recommended statistical bases include square footage for facility costs, gross salaries for employee benefits, accumulated costs for administrative and general (A&G) costs, meals served for dietary, and other bases that distribute costs in proportion to the relative benefits received, or resources consumed, by each cost center.<sup>542</sup> When a statistical basis, such as accumulated cost improperly includes costs that receive no benefit or resources, those costs included in the accumulated cost statistic must not be used to allocate cost to a department or cost center.<sup>543</sup> The MCR provides instruction for providers to adjust the accumulated cost statistics accordingly.<sup>544</sup>

Including a statistical cost that does not have a beneficial relationship to A&G expenses being allocated causes an improper distribution of overhead. Section 413.24(b)(1) explains that cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services furnished. It is the determination of these costs by the allocation of direct costs and proration of indirect costs. Section 413.24(c) sets forth that adequate cost information must be obtained from the provider's records to support payments made for services furnished to beneficiaries, and that the provider's cost information must be accurate and in sufficient detail to accomplish the purposes for which it is intended. Additionally, § 413.24(d)(6) provides specific requirements for certain purchased services and how including these costs in the accumulated cost statistic when the costs do not relate to services or resource provided by the A&G department may cause an improper distribution of overhead and could result in improper Medicare payment.

Upon review of cost report data of various provider types, we have found that providers are not utilizing the Medicare cost report instructions regarding cost allocation,<sup>545</sup> resulting in providers allocating overhead costs imprecisely which could cause inflated

<sup>540</sup> PRM–1, chapter 23, section 2307.

<sup>541</sup> PRM–1, chapter 23, section 2306.

<sup>542</sup> PRM–2, chapter 40, section 4020.

<sup>543</sup> PRM–2, chapter 40, section 4095, Table 3, ECR specifications for Worksheet B–1.

<sup>544</sup> Id.

<sup>545</sup> For example, PRM–2, chapter 40, section 4020 for hospitals.

<sup>536</sup> PRM–1, chapter 23, section 2306.

<sup>537</sup> Id.

<sup>538</sup> 42 CFR 413.24(d) and PRM–1, chapter 23, section 2306.1.

<sup>539</sup> PRM–1, chapter 23, section 2307.

<sup>535</sup> PRM–1, chapter 23, section 2302.10.

and improper reimbursement from Medicare. A&G costs can be improperly allocated when the statistic, “accumulated cost,” is used, resulting in an overinflation of the actual benefit or resources provided to various departments of the provider. As an example, when services are purchased under arrangement, the provider is paying for the complete service from an external entity. The provider’s A&G cost center does not support or benefit these external purchases and there is no relationship between the hospital’s overhead and the purchased services. Some providers are reporting the amounts paid for purchased services or products and including them in the accumulated cost statistic on their cost report. However, this is not correct. Purchased services are already fully costed by the external entity and directly assigned to the benefiting department. Including them in the accumulated cost statistic improperly allocates the provider’s overhead to a cost center that already contains the full purchase price of the service as well as the entity’s overhead costs and profit. For example, transplant hospitals that purchase organs from OPOs, and other transplant hospitals for transplantation, place the “purchase cost” for organs in the appropriate organ acquisition cost center. If these purchase costs are also included in the accumulated cost statistic used to allocate A&G costs, the overhead A&G are improperly shifted, that is allocated, to the cost center as well. The amounts paid by the transplant hospitals to OPOs or other transplant hospitals for purchased organs has increased significantly over the years. This increases improper allocation of overhead costs. Another example of this is when hospitals purchase CAR T-cell biologicals. The purchase price includes costs for the complete process of extracting and preparing the biological for infusion. Including these direct costs in the accumulated cost statistic would improperly and disproportionately allocate overhead to the CAR T-cell cost center without any relationship between the hospital’s overhead and the purchased biological. Including these purchased services, or supplies, in the accumulated cost statistic causes overhead A&G costs to shift and be allocated from the hospital’s cost centers that benefit from A&G to the cost reimbursed areas of the hospital without any causal or beneficial relationship. In this regard, including in the accumulated cost statistic the purchased services, supplies, or products that are directly assigned to a department, and

that include in the purchase price the full cost from the external entity, including overhead and profit, results in an improper and excessive allocation of overhead to the cost center.

When a provider purchases services or supplies and the amount of direct costs reported and paid to external entities includes the entities’ overhead and profit, including these costs in the accumulated cost statistic overinflates the allocation and results in improper Medicare payment to the provider. In accordance with the MCR instructions,<sup>546</sup> if costs in a cost center or department include direct assignment of purchased products, organs, or services, the provider must remove the directly assigned costs (purchased costs) from its allocation statistic to assure a proper allocation of overhead. Purchased services are reported as direct costs and must bypass the step-down allocation process. This process ensures appropriate Medicare payment and ensures that the provider’s cost centers do not receive an improper distribution of overhead costs without the overhead cost center providing support or a benefit. These longstanding Medicare cost finding principles are in accordance with § 413.24(c) and (d) and previously have been set forth in the MCR instructions.<sup>547</sup>

Similar issues with overhead allocations may exist for CAHs and some CAHs have requested that CMS clarify the cost allocation rules with more explicit cost reporting instructions. Because CAHs are reimbursed by Medicare at 101 percent of their reasonable costs, they may face undesirable financial consequences if their overhead A&G costs are improperly allocated on their cost reports. This can occur when CAHs improperly allocate their costs to all cost centers or departments of the CAH based on the accumulated cost statistic without any causal or beneficial relationship. A CAH’s costs can be shifted if they improperly allocate their costs without a causal relationship, such as to areas that do not benefit or are not serviced by overhead cost centers. This can impact the CAH’s reimbursement if an improper allocation of A&G costs reduces the calculation of the CAH’s operational costs and overall reimbursement.

We believe that the proper allocation of indirect costs by all providers is important in facilitating appropriate Medicare payment. Inflated administrative and general costs may

inaccurately increase provider payment rates resulting in increased Medicare spending.

As an example, for hospitals, there are longstanding MCR instructions in PRM–2, chapter 40, section 4020 when providers use accumulated costs as a statistic for allocation. These longstanding instructions provide two methods that a provider can use to allocate its costs when adjustments are necessary. In this regard, a provider can use either method or both methods.

The first method to adjust the allocation statistic uses a negative adjustment of either (a) a negative one (-1) in the accumulated cost column to identify the cost center which should be excluded from receiving any allocation of A&G costs; or (b) if some of the costs from that cost center are to receive A&G costs, by removing in the reconciliation column the amount of accumulated costs that are not to receive A&G costs to assure that only those costs to receive overhead receive the proper allocation. We refer to this method as the Negative Adjustment Method in this section. When direct costs are reported in a cost center or department that includes purchased services or supplies, costs other than the purchased service costs may receive an allocation of A&G costs, and the purchased service costs that are not to receive A&G must be identified and removed from the allocation statistic using the reconciliation column on Worksheet B–1. Including a statistical cost which does not relate to the allocation of A&G expenses causes an improper distribution of overhead.

If there are some costs in A&G that may have a causal relationship to the purchased service cost, a second method to correct improper allocation of overhead is set forth in the MCR instructions and PRM–1, chapter 23, section 2307.B., “*Direct Assignment of Costs to Provider Components*.” Under this method, to accommodate additional general service cost centers, the provider must add additional columns (also known as “components,” “fragments,” or “subscripts”) to the allocation worksheets, to document the step-down of a broad A&G cost center into more than one cost center and use a more accurate statistic to allocate the costs. We refer to this method as the ‘Componentizing’ of the A&G costs. In this regard, the provider establishes multiple A&G cost centers to allow for a more granular, accurate allocation to ensure that overhead costs are properly assigned to reimbursable departments. By establishing multiple A&G cost centers, providers can more precisely track and allocate overhead costs based on actual resource consumption. For

<sup>546</sup> PRM 15–2, chapter 40, section 4020.

<sup>547</sup> PRM 15–2, chapter 40, section 4020; and section 4095 for Worksheet B–1.

example, different administrative functions, such as human resources, IT, and facilities management, can be separated and allocated using different statistical bases that better reflect their utilization. Additionally, detailed cost center structures provide clearer documentation of how overhead costs are distributed, ensuring a more granular review for providers, auditors, and industry-interested parties.

For providers that desire to change their cost finding methods, PRM–1, chapter 23, section 2312 instructs providers to request this change from their Medicare contractor. This request must be submitted in writing to their contractor 90 days prior to the end of the cost reporting period to which the request for change applies. Under section 2312, the contractor’s determination of a provider’s request to change methods will be furnished to the provider in writing and will be considered binding on the provider as of the date of the contractor’s written

notice. Additionally, under section 2312, where the contractor approves the provider’s request to change methods, the provider must use this method for the cost reporting period to which the request applies and for all subsequent cost reporting periods, unless the contractor approves a subsequent request by the provider to change its cost finding methods.

In this proposed rule, we are proposing to codify these overhead cost allocation requirements that are set forth generally in existing cost reporting instructions, to ensure that providers’ costs of providing services to Medicare beneficiaries are correctly calculated. We believe this will provide additional clarity to providers so that they will correctly allocate overhead costs by ensuring that cost statistics are not used to disproportionately allocate costs resulting in inappropriate maximizing or minimizing reimbursement to providers.

Specifically, in this proposed rule we are proposing to add 413.24(d)(8) to specify that providers must not include a statistical cost which does not relate to the allocation of A&G expenses when it causes an improper distribution of overhead. For example, when a hospital performs organ transplants, it may purchase organs (kidneys, hearts, livers) from outside sources such as OPOs. These purchased organs carry a very high dollar value but have no causal relationship to administrative overhead compared to other hospital services, and these purchased organs include all the OPOs overhead in their cost. During the step-down cost allocation process on the Medicare Cost Report, when purchased organ costs are included in the accumulated cost statistic used to allocate Administrative & General (A&G) costs the allocation disproportionately allocates cost as seen in this Table X.D.-01.

TABLE X.D.-01: ADMINISTRATIVE & GENERAL (A&G) COSTS THE ALLOCATION

| Cost Center                                 | Accumulated Costs | % of Total | A&G Allocated |
|---------------------------------------------|-------------------|------------|---------------|
| Medical/Surgical Routine Care               | \$5,000,000       | 31.25%     | \$500,000     |
| ICU                                         | \$2,000,000       | 12.50%     | \$200,000     |
| Organ Acquisition (Purchased Organs)        | \$8,000,000       | 50.00%     | \$800,000     |
| Radiology                                   | \$1,000,000       | 6.25%      | \$100,000     |
| Total A&G costs to be allocated \$1,600,000 |                   | 100%       | \$1,600,000   |

When the purchased organ costs are removed from the accumulated cost statistic (as CMS guidelines instruct),

the remaining base is \$8,000,000 and the accumulated cost statistic properly

reflects the allocation of A&G costs as shown in this Table X.D.-02.

TABLE X.D.-02: ADMINISTRATIVE & GENERAL (A&G) COSTS THE ALLOCATION

| Cost Center                                 | Accumulated Costs | % of Total | A&G Allocated |
|---------------------------------------------|-------------------|------------|---------------|
| Medical/Surgical Routine Care               | \$5,000,000       | 62.50%     | \$1,000,000   |
| ICU                                         | \$2,000,000       | 25.00%     | \$400,000     |
| Organ Acquisition (Purchased Organs)        | \$0 (excluded)    | 0%         | \$0           |
| Radiology                                   | \$1,000,000       | 12.50%     | \$200,000     |
| Total A&G costs to be allocated \$1,600,000 |                   | 100%       | \$1,600,000   |

We are also proposing to add 413.24(d)(8)(i) to specify that providers must employ either a Negative Adjustment Method, or a Fragmenting (Componentizing) A&G Method, or both, to adjust the allocation statistic as it relates to accumulated costs to prevent

an improper allocation of overhead on the MCR.

We are proposing to add 413.24(d)(8)(ii) to set forth the Negative Adjustment Method for accumulated costs to specify that when direct costs are reported in a cost center or

department that includes purchased services or supplies, costs other than the purchased service costs may receive an allocation of A&G costs, and the purchased service costs that are not to receive A&G must be identified and removed. We are also proposing to add

413.24(d)(8)(ii)(A) to instruct that, on the MCR, in any column using accumulated costs as the statistical basis for allocating costs providers must identify any cost center that is not to receive an allocation by entering a negative 1 (-1) on the appropriate line in the accumulated cost column, or by entering the total accumulated cost as a negative amount on the appropriate line in the reconciliation column. For those cost centers using accumulated costs that are to receive partial allocation of costs, we are proposing to instruct providers to enter a negative amount for the costs that are to be excluded from the statistic on the appropriate line in the reconciliation column.

We are also proposing to add 413.24(d)(8)(ii)(B) to instruct providers that cost centers that are not to receive an allocation must not have entries in both the reconciliation and accumulated cost columns when the accumulated cost statistic is offset to zero. We are also proposing to add 413.24(d)(8)(ii)(C) to instruct providers that, for those cost centers that are to receive partial allocation of costs for costs other than purchased services, the cost to be excluded from the statistic must be reported as a negative amount on the appropriate line in the reconciliation column. This will result in entries in both the reconciliation column and accumulated cost column simultaneously on the same line where a partial accumulated cost statistic is offset.

In this proposed rule, we are proposing to add 413.24(d)(8)(iii) to set forth the Fragmenting (Componentizing) A&G Method, to specify that when a provider chooses to fragment, or componentize A&G costs, the provider must fragment (that is, subscript), the A&G cost center into two or more cost centers using accurate statistics to allocate its costs and ensure that overhead costs are accurately assigned to departments benefiting from the services provided. When creating multiple A&G cost centers, a provider must track and allocate overhead expenses based on actual resource consumption.

In this proposed rule, we are also proposing to add 413.24(d)(8)(iv) to specify procedures for a provider to request to change its cost finding method. We are proposing to add 413.24(d)(8)(iv)(A) to specify that a provider that wishes to change its cost finding method must submit a request to its contractor, in writing, 90 days prior to the end of the cost reporting period to which the provider's request for change applies. We are also proposing to add 413.24(d)(8)(iv)(B) to specify that

the contractor's determination of a provider's request to change methods will be furnished to the provider in writing and will be binding on the provider as of the date of the contractor's written notice. Finally, we are proposing to add 413.24(d)(8)(iv)(C) to specify that when the contractor approves the provider's request to change methods, the provider must use this method for the cost reporting period to which the request applies and for all subsequent cost reporting periods, unless the contractor approves a subsequent request by the provider to change its cost finding methods.

#### 4. Discretionary CMS Administrator Review of CMS Reviewing Official Determination With Respect to Appeals Under 42 CFR 413.420(g) for Independent Organ Procurement Organizations and Histocompatibility Laboratories

##### a. Background

Upon receipt of a provider's cost report, the Medicare contractor reviews or audits the cost report, makes any necessary adjustments to the provider's Medicare reimbursement for the cost reporting period, and finally determines the total amount of reimbursement due the provider. This year-end reconciliation of Medicare payment for the provider's cost reporting period constitutes a contractor determination, as defined in 405.1801(a). Under 42 CFR 405.1801(a)(1) and (2), and 405.1803, the contractor must give the provider written notice of the contractor determination for the cost period in a notice of the total amount of program reimbursement (NPR). The NPR is an appealable determination, subject to the jurisdictional and other requirements of the statute and regulations.

Currently, the regulations at 413.420(g) provide that an Independent Organ Procurement Organization (IOPO) or a Histocompatibility Laboratory (HCL) that is dissatisfied with a Medicare contractor's cost report determination may request a hearing before a contractor hearing officer if the amount in controversy is \$1,000 or more, in accordance with the procedures and requirements set forth in 42 CFR 405.1811 through 405.1833. Once the contractor hearing officer decision is issued, an IOPO, HCL is entitled to obtain review by a CMS reviewing official (*see* 42 CFR 405.1801(b), 405.1833, 405.1834(b) and (c)). Section 405.1834 currently specifies that the designated CMS reviewing official reviews a final decision by the contractor hearing officer and then issues a decision on

behalf of the Administrator (405.1834(a)). The CMS reviewing official, on behalf of the Administrator, currently has discretion to take own-motion review (that is, review that is not at a request of a party) of a contractor hearing officer decision (405.1834(a), (b)(1)(ii), and (d)). The CMS reviewing official decision may be reopened and revised by a CMS reviewing official in accordance with 405.1885 through 405.1889 (*see* 405.1834(f)(1)).

On May 2, 2023, the CMS Administrator issued Standing Order 2023–1, to allow IOPOs and HCLs to request that the Administrator review a CMS reviewing official decision and to confirm that the Administrator can review a CMS reviewing official decision on his or her own motion. We propose these regulatory changes to confirm, clarify, and explicitly provide that the Administrator has discretionary authority to review CMS reviewing official decisions and contractor hearing officer decisions for reimbursement appeals for IOPOs and HCLs. We are doing so for several reasons. Among other things, we are proposing these changes to provide consistency with other Agency administrative review processes, provide clearer notice of this aspect of the administrative review procedures applicable to IOPOs and HCLs, ensure that interested parties can comment, improve the quality of agency decision making, so that the agency may ultimately have clear and publicly available regulations regarding administrative review for IOPOs and HCLs on the books. These proposals are in many respects similar to the CMS proposal to codify the process by which the Administrator may exercise discretionary review when CMS de-certifies an OPO or otherwise takes action that would be subject to appeal under 42 CFR 486.314.<sup>548</sup> We are also proposing conforming changes to certain appeals regulations, as well as proposing certain changes to certain other appeals regulations for clarity.

##### b. Proposals

###### (1) Proposal for Appeals Available to IOPOs and HCLs

In this proposed rule, we are proposing to make changes to various regulatory provisions to confirm, clarify, and explicitly provide that a party to a CMS reviewing official decision may request that the Administrator review a CMS reviewing official decision, and that the Administrator may review a CMS reviewing official decision on his or her own motion, consistent with the

<sup>548</sup> 91 FR 4190, January 30, 2026.

intent of the Standing Order 2023–01. The proposed changes in this proposed rule will afford an opportunity to IOPOs and HCLs that desire to have CMS reviewing official decisions further reviewed by the Administrator. These proposed changes will also ensure that a principal officer of the United States (the CMS Administrator) will have discretionary authority to issue a final decision binding the U.S. Department of Health and Human Services. These proposed changes will also bring the § 413.420(g) appeals process into greater conformity with other CMS appeals processes that provide for discretionary Administrator review of administrative decisions rendered by agency tribunals, agency officials or other individuals. Our proposed changes are within the Secretary's general rulemaking authority under sections 1102 and 1871 of the Act.

Specifically, in this proposed rule we are proposing to revise 405.1801(a) so that it states that Administrator review means review provided for in section 1878(f) of the Act (42 U.S.C. 1395oo(f)) and 42 CFR 405.1875 and 405.1834. This proposed change reflects the changes that would be made to 405.1834 if this proposed rule is finalized.

In this proposed rule, we are also proposing to revise 405.1803(d)(1)(ii) so that it reflects the fact that a final agency decision by the Administrator is not just “as described in § 405.1875(e)(4),” but also is as described in 405.1834. This proposed change reflects the changes that would be made to 405.1834 if this proposed rule is finalized.

With respect to the required amount in controversy for the right to a contractor hearing for IOPOs and HCLs, in this proposed rule, we are proposing to revise § 405.1811(a)(2) and § 405.1811(c)(3) to specify that IOPOs and HCLs are subject to an amount in controversy as set forth in 42 CFR 413.420(g), which is \$1,000 or more.

In this proposed rule, we are also proposing to revise 42 CFR 405.1813(e)(1) and adding new (e)(1)(i), (e)(1)(ii), and (e)(1)(iii) to reflect that a contractor hearing decision denying an extension request under this section and dismissing the appeal is final and binding on the provider, unless the dismissal decision is reviewed by a CMS reviewing official in accordance with 405.1834(b)(2)(i), or the Administrator, or is reopened and revised by the contractor hearing officer(s) in accordance with 405.1885 through 405.1889. We are also proposing to revise 405.1813(e)(2) to specify that the contractor hearing officer(s) promptly sends the decision to the appropriate component of CMS

(currently the Center for Medicare). We are also proposing to add new 405.1813(e)(3), (e)(3)(i), and (e)(3)(ii) to reflect that a contractor hearing officer's decision granting an extension request is not subject to immediate review by a CMS reviewing official (as described in 405.1834(b)(3)), and any decision granting an extension request may be examined during the course of a CMS reviewing official's review of a final jurisdictional dismissal decision or a final hearing decision by the contractor hearing officer(s) (as described in 405.1834(b)(2)(i) and (ii)) or during the Administrator's review of a CMS reviewing official decision.

In this proposed rule, we are also proposing to revise 405.1814(a)(5) to reflect that final jurisdictional findings and jurisdictional dismissal decisions by the contractor hearing officer(s) are subject to the CMS reviewing official procedure in accordance with 405.1814(d) and 405.1834(b)(2)(i), and (ii), as well as the possibility of review by the Administrator. We are also proposing to revise 405.1814(c)(3) by adding paragraphs (i), (ii) and (iii) to reflect that a jurisdictional dismissal decision by the contractor hearing officer under 405.1814(c)(2) is final and binding on the parties, unless the decision is reviewed by a CMS reviewing official in accordance with 405.1834, or is subsequently reviewed by the Administrator in accordance with 405.1834, or is reopened and revised by the contractor hearing officer in accordance with 405.1885 through 405.1889.

In this proposed rule we are also proposing to revise the title of 405.1814(d) so that it would refer to jurisdictional decisions and include the possibility of Administrator review. We are proposing to revise 405.1814(d) so that it states that any finding by the contractor hearing officer as to whether he or she has jurisdiction to grant a hearing on a specific matter at issue in an appeal is not subject to further administrative review, except as provided in 405.1814(d). The revised subsection will also explain that a contractor hearing officer's jurisdictional findings as to specific matters at issue in an appeal may be reviewed solely during the course of the CMS reviewing official review of one of the contractor hearing officer decisions specified in 405.1834(b)(2), or during the course of the Administrator's review of a CMS reviewing official decision.

Regarding the reviewability of a contractor hearing officer's discovery or disclosure rulings, in this proposed rule we are also proposing to revise 405.1821(d)(2) to specify that to the

extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the contractor hearing officer(s), that portion of the discovery or disclosure ruling may immediately be reviewed by a CMS reviewing official or the Administrator in accordance with 405.1834. We are also proposing to revise 405.1821(d)(2)(i) to remove the phrase “the Administrator through” so it reflects that upon notice to the contractor hearing officer that the provider intends to seek immediate review of a ruling, or that the contractor or other affected nonparty intends to suggest that the CMS reviewing official or the Administrator, take own motion review of the ruling, the contractor hearing officer stays all proceedings affected by the ruling. To conform with this proposal, we are also proposing to revise the introductory text of 405.1821(d)(2)(iii) to delete the words “Administrator through the,” so that the first line states “If the CMS reviewing official or the Administrator . . .”

Regarding the effect of a contractor hearing officer's decision, in this proposed rule we are also proposing to amend 405.1833 by adding paragraphs (a), (a)(1), (a)(2) so that they reflect that a contractor hearing officer's decision issued in accordance with 405.1831 is final and binding on all parties to the contractor hearing and on the contractor, unless the contractor hearing officer's decision is reviewed by a CMS reviewing official, or is reviewed by a CMS reviewing official and then is in turn reviewed by the Administrator in accordance with 405.1834, or is reopened and revised by the contractor hearing officer(s) in accordance with 405.1885 through 405.1889. We are also proposing to amend 405.1833 by adding paragraph (b) to specify that final contractor hearing decisions are subject to the provisions of 405.1803(d).

In this proposed rule, we are also proposing to revise the section heading of 405.1834 so that it references the possibilities of and procedures for review by the CMS reviewing official and Administrator review of a reviewing official decision. We are also proposing to revise 405.1834(a) so that it no longer states that a review of a contractor hearing officer is conducted “on behalf of the Administrator” by a designated CMS reviewing official, and no longer indicates that the CMS reviewing official issues a decision “on behalf of the Administrator.” We are proposing that 405.1834(a) states that CMS or a provider that is a party to, and



dissatisfied with, a final decision by the contractor hearing officer(s), upon submitting a request that meets the requirements of 405.1834(c), is entitled to further administrative review of the decision by a CMS reviewing official, and that the decision may be reviewed at the discretion of first a designated CMS reviewing official and discretionary review by the Administrator. Additionally, we are proposing to revise 405.1834(a) so that it states that the review of a contractor hearing officer's decision is conducted first by a designated CMS reviewing official who considers whether the decision of the contractor hearing officer(s) is consistent with the controlling legal authority (as described in 405.1834(e)(1)) and the evidence in the record, and that the CMS reviewing official's decision may then be subject to further discretionary review by the Administrator.

We are also proposing to revise the general rules in 405.1834(b)(1)(ii) to specify that the CMS reviewing official exercises this review authority in response to a request from a provider party to the appeal that meets the requirements of 405.1834(c), or in response to a request from CMS, or may exercise his or her discretion to take own motion review. Additionally, we are proposing to revise the general rules in 405.1834(b)(4) to require the contractor hearing officer(s) to promptly send copies of any decision specified in 405.1834(b)(2) or (3), or in 405.1821(d)(2) and the underlying contractor hearing officer's administrative record to the appropriate component of CMS (currently the Center for Medicare). We are also proposing to revise § 405.1834(b)(4)(ii) to specify that the appropriate CMS component examines each contractor hearing officer decision that is reviewable under 405.1834(b)(2) or (3), or 405.1821(d)(2), along with any review requests and any other submissions made by a party or CMS in accordance with 405.1834, in order to assist the CMS reviewing official's and the Administrator's exercise of this review authority.

To correct a typographical error in 405.1834(c) regarding the granting of a provider's request for review by a CMS reviewing official, we are proposing to revise 405.1834(c)(1)(i) to change the word from "or" to "and" at the end of 405.1834(c)(1)(i). This proposed revision would reflect that a provider's request for review by a CMS reviewing official is granted if 405.1834(c)(1)(i) and 405.1834(c)(1)(ii) are met by requiring that the date of receipt by the appropriate CMS component of the review request is no later than 60 days

after the date of receipt by the provider of the contractor hearing officer decision; and the request seeks review of a decision listed in 405.1834(b)(2), and the provider complies with the requirements of 405.1834(c)(2).

Regarding a request for immediate review of a contractor hearing officer ruling authorizing discovery or disclosure, we are proposing to revise 405.1834(c)(3) and (c)(3)(i) to specify that a request from a party or CMS for immediate review of a contractor hearing officer ruling authorizing discovery or disclosure in accordance with 405.1834(b)(3) must be made as soon as practicable after the ruling is made, but in no event later than 5 business days after the date the requesting party or CMS received notice of the ruling.

To reorganize and house the provisions together in 405.1834(d) for the own motion review of a CMS reviewing official, in this proposed rule, we are proposing to revise the paragraph title of 405.1834(d) so that it states "Own motion review of a CMS reviewing official." We are also proposing to revise 405.1834(d)(1) to reflect that the CMS reviewing official has discretion to take own motion review of a contractor hearing decision (regardless of whether the decision was favorable or unfavorable to the provider) or other reviewable action. We are also proposing to add new 405.1834(d)(4) to specify that if the CMS reviewing official does not notify the parties and the contractor that he or she intends to review the contractor hearing officer decision or other reviewable action within 90 days after the date of the contractor hearing officer's decision, then the Administrator may issue a notice instructing the CMS reviewing official to review the contractor hearing officer decision and issue a decision if the CMS reviewing official fails to do so. Additionally, we are proposing to add new 405.1834(d)(4)(i) to specify that the Administrator shall promptly provide copies of the notice instructing the CMS reviewing official to review the contractor hearing officer decision to the parties, the contractor, and to the appropriate component of CMS. We are proposing to add new 405.1834(d)(4)(ii) to specify that after the CMS reviewing official's receipt of the Administrator's notice (instructing the CMS reviewing official to review the contractor hearing officer decision and issue a decision), the CMS reviewing official must allow the parties a reasonable period to comment on the issues identified by the Administrator for review. Finally, we are proposing to add new 405.1834(d)(5) to specify that if no party requests

review of the contractor hearing decision and the CMS reviewing official does not take review on its own motion or at the direction of the Administrator within the time periods specified in 405.1834(d), the contractor hearing officer decision is final in accordance with 405.1833.

Regarding the reviewing official's review procedures for contractor hearing officer's decisions, in this proposed rule, we are proposing to revise the introductory text in 405.1834(e)(1) to state "In reviewing a contractor hearing officer decision specified in paragraph (b)(2) or (b)(3) of this section, the CMS reviewing official must—." We are also proposing to revise 405.1834(e)(3) to specify that upon completion of the review of a contractor hearing decision in 405.1834(b)(2) or 405.1834(b)(3), the CMS reviewing official issues a written decision that includes findings of fact and conclusions of law on jurisdictional issues and on the merits of each issue under review over which the CMS reviewing official has jurisdiction and affirms, reverses, or modifies the contractor hearing decision or remands the contractor hearing decision to the contractor hearing officer for further proceedings. A copy of the decision must be sent promptly to each party, to the contractor, and to the appropriate component of CMS (currently the Center for Medicare).

To reflect the possibility of Administrator review of a reviewing official's decision, in this proposed rule, we are proposing to revise 405.1834(f) from "Effect of a decision: Remand" to "Effect of a reviewing official's decision, remand, and the possibility of Administrator review." We are also proposing to revise 405.1834(f)(1) to specify that a decision of affirmation, reversal, or modification by the CMS reviewing official is final and binding on each party and the contractor except as set forth in 405.1834(g). The CMS reviewing official's decision may be reopened and revised by the CMS reviewing official in accordance with 405.1885 through 405.1889. Decisions of a CMS reviewing official are subject to the provisions of 405.1803(d). A decision by a CMS reviewing official remanding an appeal to the contractor hearing officer(s) for further proceedings under 405.1834(f)(2) is not a final decision.

We are also proposing to revise the introductory text of 405.1834(f)(2) to state "A remand to the contractor hearing officer(s) by the CMS reviewing official must do all of the following:"

In this proposed rule, we are also proposing to add 405.1834(f)(3) to



specify that the CMS reviewing official must promptly send copies of the CMS reviewing official decision, along with any other submissions made by a party or CMS in accordance with the provisions of this section, to the appropriate component of CMS (currently the Center for Medicare) and to the Administrator c/o the CMS Office of the Attorney Advisor.

In this proposed rule, we are also proposing to add new paragraph (g) entitled “Administrator review of a CMS reviewing official’s decision” to 405.1834 to further specify and elaborate on the procedures for the Administrator’s review of a CMS reviewing official’s decision. Specifically, we are proposing to add 405.1834(g)(1) to specify that CMS or any party to a CMS reviewing official decision may request Administrator review of a CMS reviewing official decision in accordance with 405.1834. No other provider, individual, or entity may request review. The Administrator may grant or deny review of a CMS reviewing official decision at his or her discretion. The Administrator may also review any decision of the CMS reviewing official on his or her own motion (regardless of whether the decision was favorable or unfavorable to the provider). In this proposed rule, we are also proposing to add 405.1834(g)(2) to specify that a party, or CMS may request that the Administrator review a CMS reviewing official decision within 15 days of their receipt of a final CMS reviewing official decision. *See* 42 CFR 405.1801 (defining the term “date of receipt.”). We are also proposing to add 405.1834(g)(2)(i) to specify that all requests for Administrator review and any other submissions to the Administrator under 405.1834(g)(2) must be sent to the Office of the Attorney Advisor. The request for review must be in writing, attach a copy of the CMS reviewing official decision for which it seeks review, and include a brief description of all of the following: those aspects of the CMS reviewing official decision with which the requestor is dissatisfied; the reasons for the requestor’s dissatisfaction; any argument or record evidence the requestor believes supports its position; and any additional, extra-record evidence relied on by the provider, along with a demonstration that such evidence was improperly excluded in proceedings (as described in § 405.1823).

In this proposed rule, we are also proposing to add 405.1834(g)(2)(ii) to specify that the Administrator must issue a Notice advising the parties of his or her intent to review or to decline to

review within 30 days of the Administrator’s receipt of a request for review from CMS or any party to the CMS reviewing official’s decision. That Notice must be promptly sent to the parties, the contractor, and the appropriate component of CMS. A Notice advising the parties of the Administrator’s intent to review must contain a brief statement of the issues under “review and solicit comments from the parties, the contractor, and CMS. A Notice that the Administrator is declining to review need not set forth the basis for the Administrator’s decision to decline review the CMS reviewing official’s decision. We are also proposing to add 405.1834(g)(2)(iii) to specify that if the Administrator declines to review the reviewing official decision or the Administrator does not issue a determination regarding review of the reviewing official decision within 30 days of the Administrator’s receipt of a request to review, the decision of the CMS reviewing official is final. We are also proposing that 405.1834(g)(2)(iii) specify that upon issuance of a Notice, within 30 days of a request for Administrator review of a CMS reviewing official decision, that the Administrator is declining to review the reviewing official’s decision, the CMS reviewing official’s decision becomes final in accordance with 405.1834(f)(1).

In this proposed rule, we are also proposing to add 405.1834(g)(3) to specify that within 45 days of Administrator’s receipt of a CMS reviewing official’s decision, the Administrator may issue a Notice of Review on his or her own motion. The Notice of Review must be sent to the parties, the contractor, and the appropriate component of CMS. The Notice of Review must contain a brief statement of the issues under review and solicit comments from the parties, contractor, and CMS. If the Administrator does not issue a determination regarding his or her own motion review within 45 days of the Administrator’s receipt of a CMS reviewing official’s decision, the decision of the CMS reviewing official is final.

In this proposed rule, we are also proposing to add 405.1834(g)(4), (g)(4)(i) and (g)(4)(ii) to set forth that if the Administrator elects to review the CMS reviewing official’s decision, the Administrator will set deadlines for the parties and affected nonparties to submit comments; and the Administrator’s decision affirming, reversing, or modifying the CMS reviewing official’s decision is final and binding on each party and the contractor. A decision remanding an

appeal to the CMS reviewing official, contractor hearing officer(s) is not a final decision. Decisions of the Administrator are subject to the provisions of 405.1803(d).

In this proposed rule, we are also proposing to add 405.1834(g)(5) to specify that if the Administrator does not issue a written decision that affirms, reverses, modifies or remands the CMS reviewing official’s decision within 60 days of the date of issuance of the Notice of Review, the CMS reviewing official’s decision becomes final in accordance with 405.1834(f)(1). We are also proposing to add 405.1834(g)(6) to specify that the Administrator may remand the CMS reviewing official’s decision to the CMS reviewing official, to the contractor hearing officer, or to the contractor. A remand by the Administrator must do all of the following: vacate the CMS reviewing official’s and/or the contractor hearing officer decisions as to the specific issues remanded; be governed by the same criteria that apply to remands by the Administrator to the Board under 405.1875(f)(2), and require the entity to which the matter is remanded to take specific actions on remand; and result in the CMS reviewing official, contractor hearing officer(s), or contractor taking the actions required on remand and issuing a new decision.

#### (2) Technical and Conforming Changes at 413.420(g)

Consistent with the proposals in section X.D.4.b.(1). of the preamble of this proposed rule, we are proposing conforming revisions to the current regulations at 413.420(g) for appeals pertaining to IOPOs and HCLs. Specifically, we are proposing to revise 413.420(g) to reflect that if the amount in controversy is \$1,000 or more, any IOPO or histocompatibility laboratory that disagrees with a contractor’s cost determination is entitled to a contractor hearing, review of the contractor hearing by a CMS reviewing official, and discretionary Administrator Review of a CMS reviewing official decision, in accordance with the procedures set forth in 405.1801(b)(2) and 405.1811 through 405.1834.

#### (3) Effective Dates

In this proposed rule, we are proposing that these proposed provisions will apply to administrative appeals that were timely filed with a contractor hearing officer on or after the effective date of this rule, under 405.1811 and 405.1834, and/or that are pending before a contractor hearing officer or a CMS reviewing official on the effective date of the rule. With

respect to requests for good cause extensions under 405.1813 (for contractor hearing officer hearings), IOPOs and HCLs that have not filed a timely request for a contractor hearing and that wish to seek an extension of the time limit for filing an appeal based on good cause, have an additional 60 days after the effective date of this rule to seek an extension without meeting the “reasonable time” requirements of 405.1813 (but must meet all other requirements of that section).

#### 5. Technical Corrections and Clarifications of 412.116(c) and 413.404(b)(3)(ii)(A) and (C)

In this proposed rule, we are proposing to make several technical corrections or clarifications to the regulatory text, which are unrelated to any of the other proposals in section X.D. of the preamble of this proposed rule.

We propose to make a technical correction to 412.116(c), to change “kidney” to “organ.” This correction should have been made in our FY 2022 IPPS/LTCH PPS final rule, with comment period (86 FR 73468 through 73505), but was overlooked.

We propose to make a technical correction to 413.404(b)(3)(ii)(A) to clarify in the definition of a deceased donor SAC that the deceased donor SAC is an average organ acquisition cost that a TH incurs to procure an organ from a deceased donor. The existing regulation omits the phrase “organ acquisition.” This proposed language also mirrors the language that defines the living donor SAC.

We propose to make a technical correction to 413.404(b)(3)(ii)(C), which inadvertently omitted registry fees from the costs that transplant hospital may use to develop the deceased donor SAC. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 73477 and 73478), we included registry fees in the allowable organ acquisition costs used in developing transplant hospital living donor SACs, but inadvertently omitted registry fees from the allowable acquisition costs used to develop the transplant hospital deceased donor SACs. Registry fees would be incurred by transplant hospitals for every potential transplant recipient on their waitlist. Therefore, we propose to add 413.404(b)(3)(ii)(C)(8), to the allowable costs used to develop the deceased donor TH SAC, to include registry fees as specified at 413.402(b)(6).

## XI. MedPAC Recommendations and Publicly Available Files

### A. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC’s recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary’s recommendations regarding MedPAC’s recommendations. We have reviewed MedPAC’s March 2026 “Report to the Congress: Medicare Payment Policy” and have given the recommendations in the report consideration in conjunction with the policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2027 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC’s website at <https://www.medpac.gov>.

### B. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index>. Following is a listing of the IPPS-related data files that are available.

Commenters interested in discussing any data files used in construction of this proposed rule should contact Michael Treitel at (410) 786–4552.

#### 1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, parts II and III from FY 2023 Medicare cost reports used to create the proposed FY 2027 IPPS wage index. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.C.4. of the preamble of this proposed rule.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html>.

*Periods Available:* FY 2007 through FY 2027 IPPS Update.

#### 2. CMS Occupational Mix Data Public Use File

This file contains the CY 2022 occupational mix survey data to be used to compute the occupational mix adjusted wage indexes. Multiple versions of this file are created each

year. For a discussion of the release of different versions of this file, we refer readers to section III.C.4 of the preamble of this proposed rule.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html>.

*Period Available:* FY 2027 IPPS Update.

#### 3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital’s occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html>.

*Period Available:* FY 2027 IPPS Update.

#### 4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html>.

*Periods Available:* FY 2005 through FY 2027.

#### 5. FY 2027 IPPS FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Federal Information Processing Standards (FIPS), county name, and a list of Core Based Statistical Areas (CBSAs).

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html> (on the navigation panel on the left side of the page, click on the FY 2027 proposed rule home page or the FY 2027 final rule home page) or <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/AcuteInpatient-Files-for-Download.html>.

*Period Available:* FY 2027 IPPS Update.

#### 6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

*Media:* internet at <https://www.cms.gov/Research-Statistics-Data->

*and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year.*

(We note that data are no longer offered on a CD. All of the data collected are now available free for download from the cited website.)

#### 7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS-DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

*Media:* internet at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspectivePaymentSystem/gen/psf\\_text](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspectivePaymentSystem/gen/psf_text).

*Period Available:* Quarterly Update.

#### 8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number based on the MS-DRGs assigned to the hospital's discharges using the GROUPEX version in effect on the date of the discharge. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS-DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Files-for-Download.html>, or for the more recent data files, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html> (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

*Periods Available:* FY 1985 through FY 2027.

#### 9. MS-DRG Relative Weights (Also Table 5—MS-DRGs)

This file contains a listing of MS-DRGs, MS-DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Files-for-Download.html>, or for the more recent data files, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html> (on the navigation panel on the left side of page, click on the specific fiscal year

*for-Service-Payment/ AcuteInpatientPPS/Files-for-Download.html*, or for the more recent data files, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html> (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or the fiscal year final rule home page desired).

*Periods Available:* FY 2005 through FY 2027 IPPS Update.

#### 10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present>, or for the more recent data files, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html> (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

*Periods Available:* FY 1994 through FY 2027 IPPS Update.

#### 11. AOR/BOR File

This file contains data used to develop the MS-DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS-DRG for length of stay and standardized charges. The BOR file are "Before Outliers Removed" and the AOR file is "After Outliers Removed." (Outliers refer to statistical outliers, not payment outliers.) Two versions of this file are created each year to support the rulemaking.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Files-for-Download.html>, or for the more recent data files, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html> (on the navigation panel on the left side of page, click on the specific fiscal year

proposed rule home page or fiscal year final rule home page desired).

*Periods Available:* FY 2005 through FY 2027 IPPS Update.

#### 12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html> (on the navigation panel on the left side of the page, click on the FY 2027 proposed rule home page or the FY 2027 final rule home page) or <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Files-for-Download.html>.

*Period Available:* FY 2027 IPPS Update.

#### 13. MS-DRG Relative Weights Cost Centers File

This file provides the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center cost-to-charge ratios (CCRs) that we used in the relative weight calculation.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html> (on the navigation panel on the left side of the page, click on the FY 2027 proposed rule home page or the FY 2027 final rule home page) or <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Files-for-Download.html>.

*Period Available:* FY 2027 IPPS Update.

#### 14. Hospital Readmissions Reduction Program Supplemental File

The Hospital Readmissions Reduction Program Supplemental File is only available and updated for the final rule, when the most recent data is available. Therefore, we refer readers to the FY 2026 IPPS/LTCH PPS final rule supplemental file, which has the most recent finalized payment adjustment factor components and is the same data as would have been used to create the FY 2027 IPPS/LTCH PPS proposed rule supplemental file.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html> (on the navigation panel on the left side of the page, click on the FY 2027 proposed rule home page or the FY 2027 final rule home page) or <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html>.  
*Period Available:* FY 2027 IPPS Update.

#### 15. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for DSH-eligible hospitals as well as the supplemental payments for eligible IHS and Tribal hospitals and hospitals located in Puerto Rico for FY 2027. Variables include the data used to determine a hospital's share of uncompensated care payments, total uncompensated care payments, estimated per-claim uncompensated care payment amounts, and if applicable, supplemental payment amounts. The file supports the rulemaking.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html> (on the navigation panel on the left side of the page, click on the FY 2027 proposed rule home page or the FY 2027 final rule home page) or <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html>.  
*Period Available:* FY 2027 IPPS Update.

#### 16. New Technology Thresholds File

This file contains the cost thresholds by MS-DRG that are generally used to evaluate applications for new technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. (As discussed in section II.G. of this proposed rule, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS-DRG for that same fiscal year.) Two versions of this file are created each year to support rulemaking.

*Media:* internet at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/>

[AcuteInpatientPPS/Index.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html) (on the navigation panel on the left side of the page, click on the applicable fiscal year's proposed rule or final rule home page) or <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html>.

*Periods Available:* FY 2025 through FY 2028 applications.

## XII. Collection of Information Requirements

### A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). The following ICRs are listed in the order of appearance within the preamble (see sections II. through XI. of the preamble of this proposed rule).

### B. Collection of Information Requirements

#### 1. ICRs for the Hospital Readmissions Reduction Program

In section V.I. of the preamble of this proposed rule, we discuss our proposed updates to the Hospital Readmissions Reduction Program. Specifically, in this proposed rule, we propose to adopt the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure beginning with the FY 2029 program year. Because this measure is calculated using Medicare administrative data (Medicare Fee-for-Service Part A and Part B claims, hospital-submitted Medicare Advantage (MA) claims and MA encounter data) that are already reported to the

Medicare program for payment purposes under OMB control number 0938–1197 (expiration date October 31, 2027), and MA Organization-submitted encounter data already collected by CMS under OMB control number 0938–1152 (expiration date July 31, 2027), adopting this measure would not result in any change in information collection burden.

#### 2. ICRs for the Hospital Value-Based Purchasing Program

In section V.J. of the preamble of this proposed rule, we discuss our proposed updates to the Hospital Value-Based Purchasing Program. Specifically, we propose to modify the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization, Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization, Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization, Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization, and Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft Surgery measures beginning with the July 1, 2028–June 30, 2030 performance period, associated with the FY 2032 payment determination. The proposed modifications would include adding Medicare Advantage (MA) beneficiaries into the patient cohorts and modifying the applicable performance period from a 3-year period to a 2-year period.

The five measures we are proposing to modify currently use data that are collected using Medicare Fee-for-Service claims that hospitals are already submitting to the Medicare program for payment purposes under OMB control number 0938–1197 (expiration date October 31, 2027); therefore, there is no additional information collection burden regarding the modification of the applicable performance period. We also do not anticipate any change in burden associated with the proposed modification to add MA beneficiaries into the measure cohorts. As proposed, the measure would use MA encounter data already collected by CMS under OMB control number 0938–1152 (expiration date July 31, 2027) to determine cohort inclusion criteria, complications outcomes, and present on admission comorbidities. We discuss the burden associated with the proposals to adopt these measures under the Hospital Inpatient Quality Reporting Program in section XII.B.4.c. of the preamble of this proposed rule.

### 3. ICRs for the Hospital-Acquired Condition Reduction Program

OMB has currently approved 28,840 hours of burden and approximately \$1.5 million under OMB control number 0938–1352 (expiration date November 30, 2027), accounting for information collection burden experienced by 400 subsection (d) hospitals selected for validation each year in the Hospital-Acquired Condition Reduction Program. We are not making any proposals or updates for the Hospital-Acquired Condition Reduction Program in this proposed rule.

### 4. ICRs for the Hospital Inpatient Quality Reporting Program

#### a. Background

Data collection for the Hospital Inpatient Quality Reporting Program is associated with OMB control number 0938–1022 (expiration date December 31, 2028), under which OMB has currently approved 1,351,632 hours of burden at a cost of approximately \$73.7 million, accounting for information collection burden experienced by approximately 3,050 IPPS hospitals and 1,500 non-IPPS hospitals for the FY 2028 payment determination. In this proposed rule, we describe the burden changes regarding collection of information, under OMB control number 0938–1022.

For more detailed information on our proposals for the Hospital Inpatient Quality Reporting Program, we refer readers to sections IX.B. and IX.C. of the preamble of this proposed rule. We are proposing to adopt three new measures: (1) the Advance Care Planning electronic clinical quality measures (eCQM) beginning with the CY 2028 reporting period/FY 2030 payment determination; (2) the Hospital Harm-Postoperative Venous Thromboembolism (VTE) eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination; and (3) the Excess Days in Acute Care After Hospitalization for Diabetes measure beginning with the July 1, 2025 through June 30, 2027 performance period, associated with the FY 2029 payment determination. We are also proposing to adopt five mortality measures for the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination, through the July 1, 2027 through June 30, 2029 performance period, associated with the FY 2031 payment determination: (1) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization measure; (2) the

Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization measure beginning; (3) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure; (4) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization measure; and (5) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery measure. We are also proposing to modify three measures beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination: (1) the Excess Days in Acute Care after Hospitalization for AMI measure; (2) the Excess Days in Acute Care after Hospitalization for HF measure; and (3) the Excess Days in Acute Care after Hospitalization for Pneumonia measure. We are additionally proposing to remove three self-selected eCQMs beginning with the CY 2028 reporting period/FY 2030 payment determination: (1) the VTE Prophylaxis eCQM; (2) the Intensive Care Unit VTE Prophylaxis eCQM; and (3) Discharged on Antithrombotic Therapy eCQM. Lastly, we are proposing an update to the reporting and submission requirements for the Maternal Morbidity Structural measure beginning with the CY 2026 reporting period/FY 2028 payment determination. We do not anticipate any of these proposals will affect information collection burden.

We are proposing to modify the reporting and submission requirements for eCQMs to require mandatory reporting of the Malnutrition Care Score eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination, and to require mandatory reporting of Hospital Harm eCQMs after two years of self-selected reporting beginning with the CY 2028 reporting period/FY 2030 payment determination. We discuss the impacts on information collection burden associated with these proposals later in this section.

Using the most recent data from the BLS for medical records specialists (SOC 29–2072), entitled, the May 2024 Occupational Employment and Wage Estimates, we propose to use the median hourly wage for medical records specialists for the industry, “general medical and surgical hospitals,” which is \$27.53.<sup>549</sup> We believe the industry of

“general medical and surgical hospitals” is more specific to this program compared to other industries under medical records specialists, such as “office of physicians” or “nursing care facilities.” We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ( $\$27.53 \times 2 = \$55.06$ ) to estimate total cost is a reasonably accurate estimation method. Unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of \$55.06 per hour throughout the discussion in this section of this rule for the Hospital Inpatient Quality Reporting Program. If BLS releases updated wage rates after this proposed rule appears in the **Federal Register** and before the final rule appears in the **Federal Register**, we will maintain the wage rates used in this proposed rule.

In the FY 2026 IPPS/LTCH PPS final rule (90 FR 37192), our burden estimates were based on an assumption of approximately 3,050 IPPS hospitals. For this proposed rule, based on data from the FY 2026 Hospital Inpatient Quality Reporting Program payment determination, we are maintaining that assumption and estimate that approximately 3,050 IPPS hospitals will report data to the Hospital Inpatient Quality Reporting Program for the CY 2027 reporting period.

#### b. Information Collection Burden Estimate for the Proposed Adoption of Two eCQMs

In sections IX.B.1. and IX.C.3.b. of the preamble of this proposed rule, we discuss the proposals to adopt the Advance Care Planning eCQM and Hospital Harm-Postoperative VTE eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination, respectively, to add to the set of eCQMs from which hospitals may self-select to meet their eCQM reporting requirements. The proposed adoption of these two eCQMs would not affect the information collection burden of submitting eCQMs under the Hospital Inpatient Quality Reporting Program as current policy under OMB control number 0938–1022 requires hospitals to submit data for three self-selected and eight mandatory eCQMs from the eCQM

<sup>549</sup> U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics: General Medical

and Surgical Hospitals, Medical Records Specialists. Accessed December 29, 2025. Available at: <https://data.bls.gov/oes/#/industry/622100>.

measure set, for a total of 11 eQMs, for the CY 2028 reporting period/FY 2030 payment determination and subsequent years. In other words, although these new eQMs would be added to the eQCM measure set, hospitals would not be required to report more than a total of 11 eQMs for the FY 2030 payment determination and subsequent years. However, in section IX.C.8.c.(3). of the preamble of this proposed rule, we discuss the burden associated with the proposal to modify eQCM reporting and submission requirements to require mandatory reporting of Hospital Harm eQMs after two years of self-selected reporting beginning with the CY 2028 reporting period/FY 2030 payment determination.

**c. Information Collection Burden Estimate for the Proposed Adoption of Six Claims-Based Measures**

In sections IX.B.2. and IX.C.3.a. of the preamble of this proposed rule, we discuss the proposed adoption of six claims-based measures. In section IX.C.3.a. of the preamble of this proposed rule, we discuss the proposed adoption of one new claims-based measure: (1) Excess Days in Acute Care After Hospitalization for Diabetes measure beginning with the July 1, 2025 through June 30, 2027 performance period, associated with the FY 2029 payment determination. In section IX.B.2. of the preamble of this proposed rule, we discuss the adoption of five mortality measures beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination, through the July 1, 2027 through June 30, 2029 performance period, associated with the FY 2031 payment determination: (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following AMI Hospitalization measure; (2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following HF Hospitalization measure; (3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure; (4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following COPD Hospitalization measure; and (5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following CABG Surgery measure.

Because these measures are calculated using Medicare FFS claims that are already reported to the Medicare program for payment purposes under OMB control number 0938–1197 (expiration date October 31, 2027) and MA encounter data already collected by CMS under OMB control number 0938–1152 (expiration date July 31, 2027) to

determine cohort inclusion criteria, complications outcomes, and present on admission comorbidities, adoption of these measures would not result in a change in burden associated with OMB control number 0938–1022.

**d. Information Collection Burden Estimate for the Proposed Modification of Three Excess Days in Acute Care After Hospitalization Measures**

In section IX.C.5. of the preamble of this proposed rule, we are proposing to modify three measures beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination: (1) the Excess Days in Acute Care after Hospitalization for AMI measure; (2) the Excess Days in Acute Care after Hospitalization for HF measure; and (3) the Excess Days in Acute Care after Hospitalization for Pneumonia measure.

This proposed modification would include adding MA beneficiaries to the current cohort of patients and shortening the performance period from 3 years to 2 years. Because these measures would be calculated using Medicare FFS claims that are already reported to the Medicare program for payment purposes under OMB control number 0938–1197 and MA encounter data already collected by CMS under OMB control number 0938–1152 to determine cohort inclusion criteria, complications outcomes, and present on admission comorbidities, modifying these measures would not result in a change in burden associated with OMB control number 0938–1022.

**e. Information Collection Burden Estimate for the Proposed Removal of Three eQMs**

In section IX.C.4. of the preamble of this proposed rule, we are proposing the removal of three eQMs beginning with the CY 2028 reporting period/FY 2030 payment determination: (1) the VTE Prophylaxis eQCM; (2) the Intensive Care Unit VTE eQCM; and (3) Discharged on Antithrombotic Therapy eQCM. Because reporting these eQMs is not mandatory, but they are instead available in the Hospital Inpatient Quality Reporting Program eQCM measure set for hospitals to self-select to report, removing these eQMs would not result in a change in burden associated with OMB control number 0938–1022.

**f. Information Collection Burden Estimate for the Proposed Modification to the Reporting and Submission Requirements for the Maternal Morbidity Structural Measure**

In section IX.C.8.d.(1). of the preamble of this proposed rule, we discuss the proposal to modify the reporting and submission requirements for the Maternal Morbidity Structural measure beginning with the CY 2027 reporting period/FY 2029 payment determination. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365), we adopted the Maternal Morbidity Structural measure, requiring hospitals to attest “yes”, “no”, or “not applicable” to one two-part question. The currently approved information collection burden for the Maternal Morbidity Structural measure under OMB control number 0938–1022 is five minutes (0.083 hours) per IPPS hospital annually. We are proposing to add a sub-question to collect the name of the Statewide and/or National Perinatal Quality Improvement Collaborative Program in which the hospital participates. We believe that the currently approved burden of five minutes is adequate for hospitals to both attest to the current two-part question and answer the proposed sub-question and therefore are not proposing any changes to the currently approved burden estimate.

**g. Information Collection Burden Estimate for the Proposed Changes to eQCM Reporting and Submission Requirements**

In section IX.C.8.c.(2). of the preamble of this proposed rule, we discuss the proposal to modify the reporting and submission requirements for the Malnutrition Care Score eQCM to require mandatory reporting beginning with the CY 2028 reporting period/FY 2030 payment determination. The Malnutrition Care Score eQCM (previously known as Global Malnutrition Composite Score eQCM) was initially adopted in the FY 2023 IPPS/LTCH PPS final rule into the Hospital Inpatient Quality Reporting Program measure set from which a hospital could self-select beginning with the CY 2024 reporting period/FY 2026 payment determination (87 FR 49239 through 49246).

In section IX.C.8.c.(3). of the preamble of this proposed rule, we discuss the proposal to modify the reporting and submission requirements for Hospital Harm eQMs to require mandatory reporting after two years of self-selected reporting, beginning with the CY 2028 reporting period/FY 2030 payment

determination. In the currently approved eCQM measure set, there are two Hospital Harm eCQMs in the Hospital Inpatient Quality Reporting Program measure set from which a hospital could self-select: Hospital Harm-Falls with Injury and Hospital Harm-Postoperative Respiratory Failure. Under this proposal, these two measures would begin mandatory reporting with the FY 2030 payment determination, given they were adopted in the FY 2025 IPPS/LTCH PPS final rule for self-selection eCQMs beginning with the FY 2028 payment determination (89 FR 69534 through 69545). Additionally, as discussed in section IX.C.3.b. of the preamble of this proposed rule, we are proposing to adopt the Hospital Harm-Postoperative VTE eCQM as a self-selected eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination. If finalized, this measure would begin mandatory reporting with the FY 2032 payment determination.

Current Hospital Inpatient Quality Reporting Program policy under OMB control number 0938-1022 requires hospitals to submit data for three self-

selected and eight mandatory eQMs, for a total of 11 eQMs, for the CY 2028 reporting period/FY 2030 payment determination and subsequent years. The currently approved information collection burden per reported eQM under OMB control number 0938–1022 is 10 minutes (0.167 hours) per hospital per quarter or 40 minutes (0.67 hours) per hospital annually. For the CY 2028 reporting period/FY 2030 payment determination and CY 2029 reporting period/FY 2031 payment determination, we estimate the proposed modifications to the Malnutrition Care Score and two Hospital Harm eQMs would result in a total increase of 120 minutes (2 hours) per hospital annually (10 minutes/eQM  $\times$  3 eQMs  $\times$  4 quarters) or a total annual burden increase across all 3,050 IPPS hospitals of 6,100 hours (2 hours  $\times$  3,050 IPPS hospitals) at a cost of \$335,866 (6,100 hours  $\times$  \$55.06). Beginning with the CY 2030 reporting period/FY 2032 payment determination, when the Hospital Harm-Postoperative VTE eQM would become a mandatory eQM to report if this policy is finalized, we estimate the proposed

modifications would result in a total increase of 160 minutes (2.67 hours) per hospital annually ( $10 \text{ minutes/eCQM} \times 4 \text{ eCQMs} \times 4 \text{ quarters}$ ) or a total annual burden increase across all 3,050 IPPS hospitals of 8,133 hours ( $2.67 \text{ hours} \times 3,050 \text{ IPPS hospitals}$ ) at a cost of \$447,803 ( $8,133 \text{ hours} \times \$55.06$ ).

## h. Summary of Information Collection Burden Estimates for the Hospital Inpatient Quality Reporting Program

In summary, under OMB control number 0938–1022 (expiration date December 31, 2028), we estimate that the policies promulgated in this proposed rule would result in an increase in information collection burden of 8,133 hours at a cost of \$447,803. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1022. With respect to any costs/ burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this proposed rule).

**BILLING CODE 4120-01-P**

**TABLE XII.B-01: SUMMARY OF HOSPITAL INPATIENT QUALITY REPORTING PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 AND CY 2029 REPORTING PERIODS**

| Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2028 and CY 2029 Reporting Periods |                                        |                                    |                                 |                                                      |                                      |                                         |                                                                |                                       |
|----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|------------------------------------|---------------------------------|------------------------------------------------------|--------------------------------------|-----------------------------------------|----------------------------------------------------------------|---------------------------------------|
| Activity                                                                                                                         | Estimated Time per Record (in minutes) | Number Reporting Quarters per Year | Number of Respondents Reporting | Average Number of Records per Respondent per Quarter | Annual Burden (Hours) per Respondent | Proposed Annual Burden Across Hospitals | Previously Finalized Annual Burden (in hours) Across Hospitals | Net Difference in Annual Burden Hours |
| Modification of Malnutrition Care Score eCQM Reporting                                                                           | 10                                     | 4                                  | 3,050                           | 1                                                    | 0.67                                 | 24,406                                  | 22,367                                                         | 2,039                                 |
| Modification of Hospital Harm of QMs Reporting                                                                                   | 20                                     | 4                                  | 3,050                           | 1                                                    | 1.33                                 | 26,433                                  | 22,367                                                         | 4,066                                 |
| <b>Total Change in Information Collection Burden Hours: 6,100</b>                                                                |                                        |                                    |                                 |                                                      |                                      |                                         |                                                                |                                       |
| <b>Total Cost Estimate: Updated Hourly Wage (\$55.06) x Change in Burden Hours (6,100) = \$335,866</b>                           |                                        |                                    |                                 |                                                      |                                      |                                         |                                                                |                                       |

**TABLE XILB-02: SUMMARY OF HOSPITAL INPATIENT QUALITY REPORTING PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2030 REPORTING PERIOD**

| Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2030 Reporting Period |                                        |                                    |                               |                                                   |                                      |                                                    |                                                                |                                       |
|---------------------------------------------------------------------------------------------------------------------|----------------------------------------|------------------------------------|-------------------------------|---------------------------------------------------|--------------------------------------|----------------------------------------------------|----------------------------------------------------------------|---------------------------------------|
| Activity                                                                                                            | Estimated Time per Record (in minutes) | Number Reporting Quarters per Year | Number of Responses Reporting | Average Number Records per Respondent per Quarter | Annual Burden (Hours) per Respondent | Proposed Annual Burden (in hours) Across Hospitals | Previously Finalized Annual Burden (in hours) Across Hospitals | Net Difference in Annual Burden Hours |
| Modification of Malnutrition Care Score eCQM Reporting                                                              | 10                                     | 4                                  | 3,050                         | 1                                                 | 0.67                                 | 24,400                                             | 22,367                                                         | 2,033                                 |
| Modification of Hospital Harm eCQMs Reporting                                                                       | 30                                     | 4                                  | 3,050                         | 1                                                 | 2.0                                  | 28,467                                             | 22,367                                                         | 6,100                                 |
| <b>Total Change in Information Collection Burden Hours: 8,133</b>                                                   |                                        |                                    |                               |                                                   |                                      |                                                    |                                                                |                                       |
| <b>Total Cost Estimate:</b> Updated Hourly Wage (\$55.06) x Change in Burden Hours (8,133) = <b>\$447,803</b>       |                                        |                                    |                               |                                                   |                                      |                                                    |                                                                |                                       |



## BILLING CODE 4120-01-C

## 5. ICRs for the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program

OMB has currently approved a total of 2 hours of burden at a cost of \$111 under OMB control number 0938-1175 (expiration date January 31, 2029), accounting for the annual information collection requirements for 11 PCHs for the PCH Quality Reporting Program. In this proposed rule, we describe the burden changes regarding collection of information under OMB control number 0938-1175 for PCHs.

For more detailed information on our proposals for the PCH Quality Reporting Program, we refer readers to sections IX.B. and IX.D. of the preamble of this proposed rule. We are proposing to adopt two measures beginning with the CY 2028 reporting period/FY 2030 program year: (1) the Advance Care Planning electronic clinical quality measure (eCQM); and (2) the Malnutrition Care Score eCQM. We are also proposing to remove the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the CY 2026 reporting period/FY 2028 program year. We discuss the impacts on information collection burden associated with these proposals later in this section.

Using the most recent data from the BLS for medical records specialists (SOC 29-2072), entitled, the May 2024 Occupational Employment and Wage Estimates, we propose to use the median hourly wage for medical records specialists for the industry, “general medical and surgical hospitals,” which is \$27.53.<sup>550</sup> Because we are estimating the burden specific to PCHs, as previously assumed in the FY 2026 IPPS/LTCH PPS final rule, we believe the industry of “general medical and surgical hospitals” is more specific to this program compared to other industries under medical records specialists, such as “office of physicians” or “nursing care facilities” (90 FR 37194). We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with the FY 2026 IPPS/LTCH

PPS final rule and previous years (90 FR 37194). This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ( $\$27.53 \times 2 = \$55.06$ ) to estimate total cost is a reasonably accurate estimation method. Unless otherwise specified, we will calculate cost burden to PCHs using a wage plus benefits estimate of \$55.06 per hour throughout the discussion in this section of this rule for the PCH Quality Reporting Program. In order to maintain consistency to the extent possible between proposed and final rules, if BLS releases updated wage rates after this proposed rule appears in the **Federal Register** and before the final rule appears in the **Federal Register**, we will maintain the wage rates used in this proposed rule.

## b. Information Collection Burden Estimate for the Proposed Adoption of Two eQMs

In sections IX.B.1. and IX.D.2.a. of the preamble of this proposed rule, we discuss the proposals to adopt the Advance Care Planning and Malnutrition Care Score eQMs, respectively, beginning with the CY 2028 reporting period/FY 2030 program year. Similar to the currently approved information collection burden estimates for submission of eQMs for the Hospital Inpatient Quality Reporting Program under OMB control number 0938-1022, we assume a Medical Records Specialist would require 10 minutes (0.167 hours) per eCQM to submit the data required per quarter for each PCH, or 40 minutes (0.67 hours) annually. For both eQMs, we estimate a total of 80 minutes (1.33 hours) annually per PCH, or 15 hours across all PCHs ( $1.33 \text{ hours} \times 11 \text{ PCHs}$ ) at a cost of \$826 ( $15 \text{ hours} \times \$55.06$ ).

## c. Information Collection Burden Estimate for the Proposed Removal of the COVID-19 Vaccination Coverage Among HCP Measure

In section IX.D.3.a. of the preamble of this proposed rule, we propose to remove the COVID-19 Vaccination Coverage among HCP measure beginning with the CY 2026 reporting period/FY 2028 program year. This measure was previously finalized in the

FY 2022 IPPS/LTCH PPS final rule (86 FR 45428 through 45434), and the associated information collection is approved under OMB control number 0920-1317<sup>551</sup> (expiration date January 31, 2028).

PCHs have the option to manually enter data directly into the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network web-based application or by uploading a CSV file. CDC estimates that each PCH requires between 40 minutes (0.67 hours) to upload a CSV file and 45 minutes (0.75 hours) monthly to enter the data manually. CDC assumes that manual data entry would be completed by a Microbiologist with a wage rate of \$58.60/hour and uploading of a CSV file would be completed by an Information Technologist with a wage rate of \$56.50/hour. Therefore, we estimate that this proposal would result in a decrease in burden of between 88 hours (0.67 hours  $\times$  12 months  $\times$  11 PCHs) at a cost of \$4,972 ( $88 \text{ hours} \times \$56.50/\text{hour}$ ) and 99 hours (0.75 hours  $\times$  12 months  $\times$  11 PCHs) at a cost of \$5,801 ( $99 \text{ hours} \times \$58.60/\text{hour}$ ) annually across all 11 PCHs under OMB control number 0920-1317.

## d. Summary of Information Collection Burden Estimates for the PCH Quality Reporting Program

In summary, under OMB control number 0938-1175 (expiration November 30, 2027), we estimate that the policies promulgated in this proposed rule for the PCH Quality Reporting Program would result in an increase in information collection burden of 15 hours and \$826. We also estimate that the policies promulgated in this proposed rule for the PCH Quality Reporting Program would result in a decrease in information collection burden between 88 hours at a savings of \$4,972 and 99 hours at a savings of \$5,801 under OMB control number 0920-1317. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938-1175. With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.L. of Appendix A of this proposed rule).

<sup>550</sup> U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics: General Medical and Surgical Hospitals, Medical Records Specialists. Available at: <https://data.bls.gov/oes/#/industry/622100>.

<sup>551</sup> Available at [https://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=202509-0920-004](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202509-0920-004).



BILLING CODE 4120-01-P

**TABLE XII.B-03: SUMMARY OF PCH QUALITY REPORTING PROGRAM  
ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE FY 2030  
PROGRAM YEAR UNDER OMB CONTROL NUMBER 0938-1175**

| Activity                                                                                         | Estimated Time per Record (minutes) | Number Reporting Quarters per Year | Number of Respondents Reporting | Average Number Records per Respondent per Quarter | Annual Burden (hours) per Respondent | Proposed Annual Burden (hours) Across PCHs | Previously Finalized Annual Burden (hours) Across PCHs | Net Difference in Annual Burden Hours |
|--------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------|---------------------------------|---------------------------------------------------|--------------------------------------|--------------------------------------------|--------------------------------------------------------|---------------------------------------|
| Adoption of Advance Care Planning eCQM                                                           | 10                                  | 4                                  | 11                              | 1                                                 | 0.67                                 | 7                                          | 0                                                      | +7                                    |
| Adoption of Malnutrition Care Score eCQM                                                         | 10                                  | 4                                  | 11                              | 1                                                 | 0.67                                 | 7                                          | 0                                                      | +7                                    |
| <b>Total Change in Information Collection Burden Hours: +15*</b>                                 |                                     |                                    |                                 |                                                   |                                      |                                            |                                                        |                                       |
| <b>Total Cost Estimate: Updated Hourly Wage (\$55.06) x Change in Burden Hours (+15) = \$826</b> |                                     |                                    |                                 |                                                   |                                      |                                            |                                                        |                                       |

\* Due to rounding, total change in burden differs from the sum of burden for each proposal.

**TABLE XII.B-04: SUMMARY OF PCH QUALITY REPORTING PROGRAM  
ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE FY 2028  
PROGRAM YEAR UNDER OMB CONTROL NUMBER 0920-1317**

| Activity                                                                                            | Estimated Time per Record (minutes) | Number Reporting Quarters per year | Number of Respondents Reporting | Average Number Records per Respondent per Quarter | Annual Burden (hours) per Respondent | Proposed Annual Burden (hours) Across PCHs | Previously Finalized Annual Burden (hours) Across PCHs | Net Difference in Annual Burden Hours |
|-----------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------|---------------------------------|---------------------------------------------------|--------------------------------------|--------------------------------------------|--------------------------------------------------------|---------------------------------------|
| Removal of COVID-19 Vaccination Coverage Among HCP Measure                                          | -45*                                | 12                                 | 11                              | 1                                                 | -9                                   | 0                                          | 99                                                     | -.99                                  |
| <b>Total Change in Information Collection Burden Hours: -99</b>                                     |                                     |                                    |                                 |                                                   |                                      |                                            |                                                        |                                       |
| <b>Total Cost Estimate: Updated Hourly Wage (\$58.60) x Change in Burden Hours (-99) = -\$5,801</b> |                                     |                                    |                                 |                                                   |                                      |                                            |                                                        |                                       |

\*For purposes of this table, we state the maximum possible burden across all PCHs.

**6. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)**

As required by section 1886(m)(5)(A)(i) of the Act, an LTCH that does not meet the requirements of the LTCH QRP for a fiscal year will receive a 2-percentage point reduction to its otherwise applicable annual update for that fiscal year. We estimated that the burden associated with the LTCH QRP is the time and effort associated with complying with the requirements of the LTCH QRP.

In section IX.E.3. of the preamble of the proposed rule, we are proposing to

remove the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (HCP COVID-19 Vaccine) measure. We are also proposing, in section IX.E.4 of the preamble of the proposed rule, to remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) measure. If these proposals are finalized, both measure removals will be effective beginning with the FY 2028 LTCH QRP.

a. ICRs for Proposed Removal of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2028 LTCH QRP

In section IX.E.3. of the preamble of this proposed rule, we are proposing to remove the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) Measure (HCP COVID-19 Vaccine measure), beginning with the FY 2028 LTCH QRP. We note that the CDC would account for the burden associated with the HCP COVID-19 Vaccine measure collection under OMB control

number 0920–1317 (expiration 01/31/2028). Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under PRA package OMB control number 0920–1317 due to a waiver under section 321 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660, enacted on November 14, 1986 (NCVIA)).<sup>552</sup> However, CMS is providing an estimate of reduction in

burden and cost for LTCHs here. Consistent with the CDC's experience of collecting data using the NHSN, we estimate the removal of this measure will result in a reduction of 1 hour(s) per month to collect data for the HCP COVID–19 Vaccine measure and enter it into NHSN. We believe that this data would be entered by an administrative assistant. However, LTCHs determine the staffing resources necessary.

For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages from the BLS May 2024 National Occupational Employment and Wage Estimates.<sup>553</sup> To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in table XII.B–06.

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**TABLE XII.B-05: U.S. BUREAU OF LABOR AND STATISTICS' MAY 2024 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES**

| Occupation Title          | Occupation Code | Median Hourly Wage (\$/hr) | Other Indirect Costs and Fringe Benefit (\$/hr) | Adjusted Hourly Wage (\$/hr) |
|---------------------------|-----------------|----------------------------|-------------------------------------------------|------------------------------|
| Administrative Assistants | 43-6013         | \$21.91                    | \$21.91                                         | \$43.82                      |

We estimate that the removal of the HCP COVID–19 measure from the LTCH QRP will result in a reduction of 12 hours per LTCH per year. Using FY 2025 data, we estimate a total of 318 LTCHS annually for a decrease of 3,816

hours (12 hours × 318 LTCHS) for all LTCHs. Given an estimated \$43.82 hourly wage for administrative assistants, we estimate a decrease of \$525.84 per LTCH (12 hours × \$43.82), or a decrease of \$167,217.12 for all

LTCHs annually (\$525.84 × 318 LTCH). The total revised annual cost increase beginning with the FY 2028 LTCH QRP related to this information collection is summarized in Table XII.B–06.

**TABLE XII.B-06: ESTIMATED BURDEN ASSOCIATED WITH COLLECTION OF THE HCP COVID-19 VACCINE MEASURE BEGINNING WITH THE FY 2028 LTCH QRP**

| Requirement                                          | Per LTCH                      |                       | All LTCHs                     |                       |
|------------------------------------------------------|-------------------------------|-----------------------|-------------------------------|-----------------------|
|                                                      | Change in Annual Burden Hours | Change in Annual Cost | Change in Annual Burden Hours | Change in Annual Cost |
| Proposed Removal of the HCP COVID-19 Vaccine Measure | -12.00                        | -\$525.84             | -3,960                        | \$167,217.12          |

b. ICRs for Proposed Removal of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning With the FY 2028 LTCH QRP

In section IX.E.4. of the preamble of this proposed rule, we are proposing to remove COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure (Patient/Resident COVID–19 Vaccine measure), beginning with the FY 2028 LTCH QRP. We believe that data collection would be completed equally by a Registered Nurse (RN) and a Licensed Practical and Licensed Vocational Nurse (LPN/LVN). However, LTCHs determine the staffing resources necessary. In section IX.E.4 of the

proposed rule we also propose to remove the item (O0350) from the LCDS, currently approved under OMB control number 0938–1163 (Expiration date: 10/31/2027). The following is a discussion of this information collection.

The net result of removing the related Patient/Resident COVID–19 Vaccine Status measure and the LCDS item used to collect the measure data (O0350. Patient COVID–19 vaccination is up to date) is a decrease of 0.3 minutes or 0.005 hour of clinical staff time. We estimate that the burden and cost for LTCHs for complying with requirements of the FY 2028 LTCH QRP would decrease under this proposal.

For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages for these staff from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates.<sup>554</sup> To account for other indirect costs and fringe benefits, we doubled the hourly wage. These amounts are detailed in Table G3. We established a composite cost estimate using our adjusted wage estimates. The composite estimate of \$78.16/hr was calculated by weighting each adjusted hourly wage equally (that is, 50 percent) [(\$61.68/hr × 0.5) plus (\$94.64/hr × 0.5) = \$78.16].

<sup>552</sup> Section 321 of the NCVIA provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (<https://www.govinfo.gov/content/pkg/USCODE-2023-title42/pdf/USCODE-2023-title42-chap6A-subchapXIX-part1-sec300aa-2.pdf>). Section 321 is not codified in the U.S. Code

but can be found in a note (<https://www.govinfo.gov/content/pkg/USCODE-2023-title42/pdf/USCODE-2023-title42-chap6A-subchapXIX-part1-sec300aa-1.pdf>).

<sup>553</sup> U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage

Estimates. [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm).

<sup>554</sup> U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics. May 2024. [https://www.bls.gov/oes/current/oes\\_stru.htm](https://www.bls.gov/oes/current/oes_stru.htm).

**TABLE XII.B-07: U.S. BUREAU OF LABOR AND STATISTICS' MAY 2024 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES**

| Occupation Title                                           | Occupation Code | Median Hourly Wage (\$/hr) | Other Indirect Costs and Fringe Benefit (\$/hr) | Adjusted Hourly Wage (\$/hr) |
|------------------------------------------------------------|-----------------|----------------------------|-------------------------------------------------|------------------------------|
| Licensed Practical and Licensed Vocational Nurse (LPN/LVN) | 29-2061         | \$30.84                    | \$30.84                                         | \$61.68                      |
| Registered Nurse (RN)                                      | 29-1141         | \$47.32                    | \$47.32                                         | \$94.64                      |

Using FY 2025 data, we estimate an annual total of 102,590 discharges from 318 LTCHs for an annual decrease of 512.95 hours ( $102,590 \times 0.005$  hour) for all LTCHs. Given 0.005 hours at \$78.16 per hour, we estimate the total cost will

decrease annually by \$40,092.17 for all LTCHs ( $\$78.16 \times 512.95$  hours). For each LTCH, we estimate an annual burden decrease of 1.61 hours (512.95 hours/318 LTCHs) and an annual decreased cost of \$126.08. The total

estimated annual burden decrease associated with the removal of the Patient/Resident COVID-19 Vaccine Status item (O0350) on discharge beginning with the FY LTCH QRP is summarized in Table XII.B-08.

**TABLE XII.B-08: ESTIMATED BURDEN ASSOCIATED WITH OMB CONTROL NUMBER 0938-1163 (CMS-10409) BEGINNING WITH THE FY 2028 LTCH QRP**

| Requirement                                               | Per LTCH                      |                       | All LTCHs                     |                       |
|-----------------------------------------------------------|-------------------------------|-----------------------|-------------------------------|-----------------------|
|                                                           | Change in Annual Burden Hours | Change in Annual Cost | Change in Annual Burden Hours | Change in Annual Cost |
| Proposed Removal of the Patient/Resident COVID-19 Measure | -1.61                         | -\$126.08             | -513                          | -\$40,092.17          |

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We invite public comments on the proposed modification to information collection requirements for LTCH QRP beginning with the FY 2028 LTCH QRP.

#### 7. ICRs for the Medicare Promoting Interoperability Program

##### a. Background

OMB has currently approved 30,151 hours of burden at a cost of \$1,669,707 under OMB control number 0938-1278 (expiration date March 31, 2029), accounting for information collection burden experienced by approximately 3,150 eligible hospitals and 1,400 Critical Access Hospitals (CAHs) for the electronic health record (EHR) reporting period in CY 2026. The collection of information burden analysis in this proposed rule focuses on all eligible hospitals and CAHs that could participate in the Medicare Promoting Interoperability Program and report the objectives and measures, and report electronic clinical quality measures (eCQMs), under the Medicare Promoting Interoperability Program for the EHR reporting periods in CY 2026 and CY 2027.

For more detailed information on our proposals for the Medicare Promoting Interoperability Program, we refer readers to section IX.B. and IX.F. of the preamble of this proposed rule. For the Medicare Promoting Interoperability Program, we are proposing to adopt three new measures: (1) the Advance Care Planning eCQM beginning with the CY 2028 reporting period; (2) the Hospital Harm-Postoperative Venous Thromboembolism (VTE) eCQM

beginning with the CY 2028 reporting period; and (3) the Unique Device Identifiers for Implantable Medical Devices measure beginning with the EHR reporting period in CY 2027. Additionally, we are proposing to remove two attestations and five measures: (1) the Office of the National Coordinator for Health Information Technology (ONC) Direct Review Attestation beginning with the EHR reporting period in CY 2026; (2) the optional ONC-Authorized Certification Body (ONC-ACB) Surveillance Attestation beginning with the EHR reporting period in CY 2026; (3) the Support Electronic Referral Loops by Sending Health Information measure beginning with the EHR reporting period in CY 2028; (4) the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure beginning with the EHR reporting period in CY 2028; (5) the VTE Prophylaxis eCQM beginning with the CY 2028 reporting period; (6) the Intensive Care Unit VTE Prophylaxis eCQM beginning with the CY 2028 reporting period; and (7) the Discharged on Antithrombotic Therapy eCQM beginning with the CY 2028 reporting period. We are also proposing to update the Electronic Prior Authorization measure by modifying the measure text, modifying the ONC certification criteria eligible hospitals and CAHs must use to attest "Yes" beginning with the EHR reporting period in CY 2027, as well as proposing to make the measure optional for the EHR reporting period in CY 2027 and required beginning with the EHR reporting period in CY 2028.

We are proposing to modify the Malnutrition Care Score eCQM to require mandatory reporting beginning with the CY 2028 reporting period. For those Hospital Harm eCQMs that are not already required to be reported (including any we may propose to adopt in the future), we are also proposing to modify the eCQM reporting and submission requirements for Hospital Harm eCQMs to require mandatory reporting after 2 years of self-selected reporting beginning with the CY 2028 reporting period. We will discuss the impacts on information collection burden associated with these proposals later in this section.

We are also proposing to revise the definition of CEHRT at 42 CFR 495.4 for the Medicare Promoting Interoperability Program so the definition would be consistent with the proposed modification to health IT certification criteria in the HTI-5 proposed rule. There is no information collection burden associated with this proposal.

Using the most recent data from the BLS for medical records specialists (SOC 29-2072), entitled, the May 2024 Occupational Employment and Wage Estimates, we propose to use the median hourly wage for medical records specialists for the industry, "general medical and surgical hospitals," which is \$27.53.<sup>555</sup> We believe the industry of "general medical and surgical hospitals" is more specific to this

<sup>555</sup> U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics: General Medical and Surgical Hospitals, Medical Records Specialists. Accessed December 29, 2025. Available at: <https://data.bls.gov/oes/#/industry/622100>.

program compared to other industries under medical records specialists, such as “office of physicians” or “nursing care facilities.” We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ( $\$27.53 \times 2 = \$55.06$ ) to estimate total cost is a reasonably accurate estimation method. Unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of \$55.06 per hour throughout the discussion in this section of this rule for the Medicare Promoting Interoperability Program. If BLS releases updated wage rates after this proposed rule appears in the **Federal Register** and before the final rule appears in the **Federal Register**, we will maintain the wage rates used in this proposed rule.

In the FY 2026 IPPS/LTCH PPS final rule (90 FR 37199), our burden estimates were based on an assumption of 4,550 eligible hospitals and CAHs. For this FY 2027 proposed rule, based on data from the EHR reporting period in CY 2024, we continue to estimate approximately 3,150 eligible hospitals and 1,400 CAHs will be eligible to report data to the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2027, for a total number of 4,550 respondents.

#### b. Information Collection Burden for the Proposed Adoption of Two eCQMs

In sections IX.B.1. and IX.F.9.b. of the preamble of this proposed rule, we are proposing to adopt two new eCQMs beginning with the CY 2028 reporting period, respectively: (1) the Advance Care Planning eCQM and (2) the Hospital Harm-Postoperative VTE eCQM, to add to the set of eCQMs from which CAHs may self-select to meet their eCQM reporting requirements. The proposed adoption of these two eCQMs would not affect the information collection burden of submitting eCQMs under the Medicare Promoting Interoperability Program as currently estimated under OMB control number 0938–1022, which accounts for eligible hospitals and CAHs submitting data for three self-selected and eight mandatory eCQMs, for a total of 11 eCQMs, from the eCQM measure set for the CY 2028 reporting period and subsequent years. In other words, although these two eCQMs would be added to the eCQM measure set, eligible hospitals and CAHs are not currently required to

report more than a total of 11 eCQMs for the CY 2028 reporting period and subsequent years. However, we note that if the proposals to modify eCQM reporting and submission requirements for the Malnutrition Care Score eCQM and all Hospital Harm eCQMs discussed in section IX.F.9.c. of this proposed rule are finalized, eligible hospitals and CAHs would be required to report a total of 14 eCQMs for the CY 2028 and CY 2029 reporting periods, and 15 eCQMs beginning with the CY 2030 reporting period. In section XII.B.7.h, we discuss the burden associated with the proposals to modify eCQM reporting and submission requirements to require mandatory reporting for the Malnutrition Care Score and all Hospital Harm eCQMs after two years of self-selected reporting beginning with the CY 2028 reporting period.

#### c. Information Collection Burden Estimate for the Proposed Adoption of the Unique Device Identifiers for Implantable Medical Devices Measure

In section IX.F.6. of the preamble of this proposed rule, we discuss the proposal to adopt the Unique Device Identifiers for Implantable Medical Devices measure under the Public Health and Clinical Data Exchange objective beginning with the EHR reporting period in CY 2027. For this attestation-based measure, eligible hospitals and CAHs would be required to report a “Yes” response, a “No” response, or claim an applicable exclusion for which they are eligible. Like other attestations approved for the Public Health and Clinical Data Exchange objective under OMB control number 0938–1278, we assume eligible hospitals and CAHs require 30 seconds (0.5 minutes) to attest to this measure. Therefore, we estimate a total annual burden increase across all 4,550 eligible hospitals and CAHs of 38 hours ( $0.0083 \text{ hours} \times 4,550 \text{ eligible hospitals and CAHs}$ ) at a cost of \$2,092 ( $38 \text{ hours} \times \$55.06$ ). As stated in section IX.F.6.b. of the preamble of this proposed rule, we note that the ONC certification criterion at 45 CFR 170.315(g)(10) can support fulfillment of the measure. Eligible hospitals and CAHs are also already required to record and maintain patient-linked implantable device information in their records under 21 CFR 821.30. Additionally, as approved by OMB under control number 0938–1022 for the Hospital Inpatient Quality Reporting Program, in which we account for the information collection burden associated with eCQM reporting and submission for eligible hospitals and CAHs, only the time associated with electronically submitting data to CMS is

accounted for in our burden estimates because patient data are already entered into EHRs and health information technology systems as part of clinical practice. Therefore, we assume no additional information collection burden under OMB control number 0938–1270 associated with entry of Unique Device Identifier information into EHRs by eligible hospitals and CAHs.

#### d. Information Collection Burden Estimate for the Proposed Removal of the ONC Direct Review and Optional ONC–ACB Surveillance Attestations

In section IX.F.3. of the preamble of this proposed rule, we discuss the proposals to remove the ONC Direct Review and optional ONC–ACB Surveillance attestations beginning with the EHR reporting period in CY 2026. The information collection burden associated with the ONC Direct Review attestation is currently approved under OMB control number 0938–1278 and assumes each eligible hospital and CAH requires 1 minute (0.0167 hours) at a cost of \$1 ( $0.0167 \text{ hours} \times \$55.06$ ) annually to attest “Yes” or “No.” We therefore estimate a total annual burden decrease across all 4,550 eligible hospitals and CAHs of 76 hours ( $0.0167 \text{ hours} \times 4,550 \text{ eligible hospitals and CAHs}$ ) at a savings of \$4,185 ( $76 \text{ hours} \times \$55.06$ ). Similarly, we estimate each eligible hospital and CAH that currently elects to submit the optional ONC–ACB Surveillance attestation will experience a decrease in burden of 1 minute (0.0167 hours) at a savings of \$1 ( $0.0167 \text{ hours} \times \$55.06$ ) annually. We therefore estimate a total annual burden decrease across all 4,550 eligible hospitals and CAHs of 76 hours ( $0.0167 \text{ hours} \times 4,550 \text{ eligible hospitals and CAHs}$ ) at a savings of \$4,185 ( $76 \text{ hours} \times \$55.06$ ). We note that although the ONC–ACB Surveillance attestation was finalized in the CY 2017 Quality Payment Program final rule with comment period (81 FR 77019 through 77028), the associated information collection burden has not been accounted for under OMB control number 0938–1278. We will submit a revised Information Collection Request under this OMB control number reflecting the inclusion of this attestation as well as its proposed removal.

**e. Information Collection Burden Estimate for the Proposed Removal of the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information Measures**

In section IX.F.4. of the preamble of this proposed rule, we discuss the proposals to remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2028. Under OMB control number 0938–1278, eligible hospitals and CAHs are currently required to report one of three alternatives under the Health Information Exchange objective: (1) the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures; (2) the Health Information Exchange (HIE) Bi-Directional Exchange measure; or (3) the Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) measure. Because eligible hospitals and CAHs would still be required to report either the HIE Bi-Directional Exchange or Enabling Exchange Under the TEFCA measure, we are not proposing any change to information collection burden associated with this proposal.

**f. Information Collection Burden Estimate for the Proposed Removal of Three eCQMs**

In section IX.F.9.b. of the preamble of this proposed rule, we are proposing the removal of three eCQMs beginning with the CY 2028 reporting period: (1) the VTE Prophylaxis eCQM; (2) the Intensive Care Unit VTE Prophylaxis eCQM; and (3) the Discharged on Antithrombotic Therapy eCQM.

The burden associated with eligible hospitals and CAHs submitting eCQMs is currently approved under OMB control number 0938–1022. Because reporting these eCQMs is not mandatory, but they are instead available in the Medicare Promoting Interoperability Program eCQM measure set for eligible hospitals and CAHs to self-select to report, removing these eCQMs would not result in a change in burden associated with OMB control number 0938–1022.

**g. Information Collection Burden Estimate for the Proposed Updates to the Electronic Prior Authorization Measure**

In section IX.F.5. of the preamble of this proposed rule, we discuss the proposed updates to the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027. Specifically, we are proposing that eligible hospitals and CAHs must use technology certified to the criteria at 45 CFR 170.315(g)(31), (32), and (33) to report on the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027. We are also proposing to modify the Electronic Prior Authorization measure description such that for at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT. Because the Electronic Prior Authorization measure is currently approved under OMB control number 0938–1278 and we are only proposing to update the criteria which eligible hospitals and CAHs would have to meet to attest “Yes”, we are not proposing any changes to information collection burden associated with this proposal.

In section IX.F.5.d. of the preamble of this proposed rule, we are proposing to make the Electronic Prior Authorization measure optional for the EHR reporting period in CY 2027 and eligible for 10 bonus points. We are also proposing to make the Electronic Prior Authorization measure required beginning with the EHR reporting period in CY 2028. Under OMB control number 0938–1278, the currently approved burden estimate for this measure is 0.5 minutes per eligible hospital and CAH. Because we are unable to estimate the number of eligible hospitals and CAHs which may elect not to attest to this measure for the EHR reporting period in CY 2027 as a result of this proposal, for burden purposes, we propose not to make any changes to the currently approved burden estimates.

**h. Information Collection Burden Estimate for the Proposed Changes to eCQM Reporting and Submission Requirements for CAHs**

In section IX.F.9.c. of the preamble of this proposed rule, we discuss the proposal to modify the reporting and submission requirements for the Malnutrition Care Score eCQM to require mandatory reporting beginning with the CY 2028 reporting period. The Malnutrition Care Score eCQM

(previously known as Global Malnutrition Composite Score eCQM) was initially adopted in the FY 2023 IPPS/LTCH PPS final rule into the Medicare Promoting Interoperability Program measure set from which an eligible hospital or CAH could self-select to report beginning with the CY 2024 reporting period (87 FR 49361 through 49364).

In section IX.F.9.c. of the preamble of this proposed rule, we discuss the proposal to modify the eCQM reporting and submission requirements for all Hospital Harm eCQMs to begin mandatory reporting after two years of self-selected reporting beginning with the CY 2028 reporting period. This proposal would apply only to Hospital Harm eCQMs that are not already required to be reported, including any Hospital Harm eCQMs we may adopt in future rules. In the currently approved eCQM measure set, there are two Hospital Harm eCQMs in the Medicare Promoting Interoperability Program measure set from which an eligible hospital or CAH could self-select: Hospital Harm-Falls with Injury and Hospital Harm-Postoperative Respiratory Failure. Under this proposal, these two measures would begin mandatory reporting with the CY 2028 reporting period, given they were adopted in the FY 2025 IPPS/LTCH PPS final rule for self-selection eCQMs beginning with the CY 2026 reporting period (89 FR 69621 and 69622). Additionally, as discussed in section IX.F.9.b. of the preamble of this proposed rule, we are proposing to adopt the Hospital Harm-Postoperative VTE eCQM as a self-selected eCQM beginning with the CY 2028 reporting period. If finalized, this measure would begin mandatory reporting with the CY 2030 reporting period.

Currently for the Medicare Promoting Interoperability Program’s eCQM reporting requirements, the information collection burden is estimated under OMB control number 0938–1022 and the policy requires eligible hospitals and CAHs to submit data for three self-selected and eight mandatory eCQMs, for a total of 11 eCQMs, for the CY 2028 reporting period and subsequent years. The currently approved information collection burden per reported eCQM under OMB control number 0938–1022 is 10 minutes (0.167 hours) per eligible hospital or CAH per quarter or 40 minutes (0.67 hours) annually. For the CY 2028 and CY 2029 reporting periods, we estimate the proposed modifications to the Malnutrition Care Score and two Hospital Harm eCQMs would result in a total increase of 120 minutes (2 hours) per CAH annually (10 minutes/eCQM ×

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| Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1278 for the CY 2026 Reporting Period |                                        |                                    |                                 |                                                   |                                      |                                                    |                                                                |                                       |
|---------------------------------------------------------------------------------------------------------------------|----------------------------------------|------------------------------------|---------------------------------|---------------------------------------------------|--------------------------------------|----------------------------------------------------|----------------------------------------------------------------|---------------------------------------|
| Activity                                                                                                            | Estimated Time per Record (in minutes) | Number Reporting Quarters per Year | Number of Respondents Reporting | Average Number Records per Respondent per Quarter | Annual Burden (Hours) per Respondent | Proposed Annual Burden (in hours) Across Hospitals | Previously Finalized Annual Burden (in hours) Across Hospitals | Net Difference in Annual Burden Hours |
| Removal of ONC Direct Review Attestation                                                                            | 1                                      | 1                                  | 4,550                           | 1                                                 | 0.0167                               | 0                                                  | 76                                                             | -76                                   |
| Removal of ONC-ACB Surveillance Attestation                                                                         | 1                                      | 1                                  | 4,550                           | 1                                                 | 0.0167                               | 0                                                  | 76                                                             | -76                                   |
| Adoption of Unique Device Identifiers for Implantable Medical Devices Attestation                                   | 0.5                                    | 1                                  | 4,550                           | 1                                                 | 0.083                                | 38                                                 | 0                                                              | +38                                   |
| <b>Total Change in Information Collection Burden Hours: -114</b>                                                    |                                        |                                    |                                 |                                                   |                                      |                                                    |                                                                |                                       |
| <b>Total Cost Estimate:</b> Updated Hourly Wage (\$55.06) x Change in Burden Hours (-114) = <b>-\$6,278</b>         |                                        |                                    |                                 |                                                   |                                      |                                                    |                                                                |                                       |

**TABLE XII.B-11: SUMMARY OF MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 AND CY 2029 REPORTING PERIODS**

| Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2028 and CY 2029 Reporting Periods |                                        |                                    |                                 |                                                   |                                      |                                                    |                                                                |                                       |
|----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|------------------------------------|---------------------------------|---------------------------------------------------|--------------------------------------|----------------------------------------------------|----------------------------------------------------------------|---------------------------------------|
| Activity                                                                                                                         | Estimated Time per Record (in minutes) | Number Reporting Quarters per Year | Number of Respondents Reporting | Average Number Records per Respondent per Quarter | Annual Burden (Hours) per Respondent | Proposed Annual Burden (in hours) Across Hospitals | Previously Finalized Annual Burden (in hours) Across Hospitals | Net Difference in Annual Burden Hours |
| Modification of Malnutrition Care Score eCQM                                                                                     | 10                                     | 4                                  | 1,500                           | 1                                                 | 0.67                                 | 12,000                                             | 11,000                                                         | 1,000                                 |
| Modification of Hospital Harm eCQMs                                                                                              | 20                                     | 4                                  | 1,500                           | 1                                                 | 1.33                                 | 13,000                                             | 11,000                                                         | 2,000                                 |
| <b>Total Change in Information Collection Burden Hours: 3,000</b>                                                                |                                        |                                    |                                 |                                                   |                                      |                                                    |                                                                |                                       |
| <b>Total Cost Estimate: Updated Hourly Wage (\$55.06) x Change in Burden Hours (3,000) = \$165,180</b>                           |                                        |                                    |                                 |                                                   |                                      |                                                    |                                                                |                                       |

**TABLE XII.B-12: SUMMARY OF MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2030 REPORTING PERIOD**

| Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2030 Reporting Period |                                        |                                    |                                 |                                                   |                                      |                                                    |                                                                |                                       |
|---------------------------------------------------------------------------------------------------------------------|----------------------------------------|------------------------------------|---------------------------------|---------------------------------------------------|--------------------------------------|----------------------------------------------------|----------------------------------------------------------------|---------------------------------------|
| Activity                                                                                                            | Estimated Time per Record (in minutes) | Number Reporting Quarters per Year | Number of Respondents Reporting | Average Number Records per Respondent per Quarter | Annual Burden (Hours) per Respondent | Proposed Annual Burden (in hours) Across Hospitals | Previously Finalized Annual Burden (in hours) Across Hospitals | Net Difference in Annual Burden Hours |
| Modification of Malnutrition Care Score eCQM                                                                        | 10                                     | 4                                  | 1,500                           | 1                                                 | 0.67                                 | 12,000                                             | 11,000                                                         | 1,000                                 |
| Modification of Hospital Harm eCQMs                                                                                 | 30                                     | 4                                  | 1,500                           | 1                                                 | 2.00                                 | 14,000                                             | 11,000                                                         | 3,000                                 |
| <b>Total Change in Information Collection Burden Hours: 4,000</b>                                                   |                                        |                                    |                                 |                                                   |                                      |                                                    |                                                                |                                       |
| <b>Total Cost Estimate: Updated Hourly Wage (\$55.06) x Change in Burden Hours (4,000) = \$220,240</b>              |                                        |                                    |                                 |                                                   |                                      |                                                    |                                                                |                                       |

**BILLING CODE 4120-01-C**

**8. ICRs for the Transforming Episode Accountability Model**

In section X.A. of the preamble of this final rule, we discuss testing the Transforming Episode Accountability Model (TEAM), proposed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), and proposed updates to the model under the authority of the CMS Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. As stated in section 1115A(d)(3) of the Act, chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule for TEAM need not be reviewed by the Office of Management and Budget.

**9. ICRs for the Comprehensive Care for Joint Replacement Expanded (CJR-X) Model**

In section X.C. of the preamble of this proposed rule, we discuss testing the proposed Comprehensive Care for Joint

Replacement Expanded (CJR-X) Model, under the authority of the CMS Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. As stated in section 1115A(d)(3) of the Act, chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule for CJR-X need not be reviewed by the Office of Management and Budget.

**10. ICRs for Proposals Regarding Acquisition Costs, Reasonable Costs, and Other Cost-Related Policies**

In section X.D.2. and in section X.D.3. of the preamble of this proposed rule, we propose to revise and codify Medicare's reasonable cost policies and cost allocation policies, and in section X.D.4. of the preamble of this proposed rule to codify the discretionary Administrator review of CMS reviewing official determinations for IOPOs and HCLs. In section X.D.5 of the preamble of this proposed rule, we propose

clarifications and technical corrections to regulation text. In addition, we propose in section X.D.1. of the preamble of this proposed rule to reconcile non-renal organ acquisition costs for IOPOs and HCLs and to require the contractor to establish, adjust if necessary, and publish interim rates for IOPOs and HCLs, with a 1-year delay, effective for cost reporting periods beginning on or after October 1, 2027.

Our proposal in section X.D.1. of the preamble of this proposed rule to reconcile non-renal organ acquisition costs for IOPOs and HCLs has a 1-year delay to allow time to update the IOPO and HCL Medicare cost report should this proposal be finalized. There would be no additional data collection requirements for IOPOs and HCLs as a result of our proposals, because IOPOs and HCLs already collect the data needed for the contractor to establish, adjust (if necessary), and publish non-renal SACs or testing rates, and to reconcile non-renal organ acquisition costs for IOPOs and HCLs, in accordance with §§ 413.20 and 413.24. However, we recognize there may be additional reporting requirements if our proposals are finalized.

The methods of determining costs payable under Medicare involve making use of data available from the

institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services. Burden hours for each OPO/HCL are the estimated time required (number of hours) to complete ongoing data gathering and recordkeeping tasks, search existing data resources, review instructions, and complete the OMB number 0938–0102, Form CMS–216–94. Currently there are 94 Medicare certified OPOs/HCLs that file Form CMS–216–94 annually. The current estimated average burden per OPO/HCL is 45 hours (30 hours for recordkeeping and 15 hours for reporting). For this proposal, we do not estimate additional recordkeeping burden but estimate an average additional reporting burden of 10 hours per OPO/HCL and an estimated additional cost of \$785.40 per OPO/HCL. The most recent median hourly wage data is available from the Bureau of Labor Statistics using their national table (available at <https://www.bls.gov/oes/tables.htm>). The median hourly wage for Category 13–2011 (accounting and audit professionals) is \$39.27. We added 100% of the median wage to account for fringe benefits and overhead costs, which calculates to \$78.54 (\$39.27 + \$39.27) and multiplied it by 10 hours, to determine the additional annual reporting costs per OPO/HCL to be \$785.40 (\$78.54 × 10 hours). We recognize this average reporting burden varies depending on the OPO/HCL's size and complexity. Because there are 94 IOPOs and HCLs, the total reporting burden cost for all IOPOs and HCLs would be \$73,828 (94 × \$785.40). We invite public comment on the hours estimate as well as the staffing requirements utilized to compile and complete the Medicare cost report. Because we proposed a 1-year delay, if our proposals were to be finalized, these estimated reporting burden would not occur until FY 2028.

CMS currently collects data on OMB control number 0938–0102, Form CMS–216–94, and if this proposal is finalized, revisions to OMB control number 0938–0102 would be included in a future PRA package notice as required under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). There are no new collection of information requirements resulting from any of our proposals in sections X.D.2., X.D.3., X.D.4., and X.D.5 of the preamble of this proposed rule.

#### XIV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them

individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 1, 2026.

#### List of Subjects

##### 42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare Reporting and recordkeeping requirements, Rural areas, X-rays.

##### 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, and Reporting and recordkeeping requirements.

##### 42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, and Reporting and recordkeeping requirements.

##### 42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

##### 42 CFR Part 419

Hospitals, Medicare, and Reporting and recordkeeping requirements.

##### 42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

##### 42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services is proposing to amend 42 CFR Chapter IV as set forth below:

#### PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

**Authority:** 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

#### § 405.1801 [Amended]

■ 2. In § 405.1801 paragraph (a) is amended in the definition of Administrator review by removing the reference “§ 405.1875” and adding in its place the reference “§§ 405.1834 and 405.1875”.

■ 3. Section 405.1803 is amended by revising paragraph (d)(1)(ii) to read as follows:

#### § 405.1803 Contractor determination and notice of amount of program reimbursement.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ii) A final decision by a CMS reviewing official (as described in § 405.1834(f)(1) of this subpart) or the Administrator (as described in §§ 405.1834 and 405.1875(e)(4) of this subpart) following review of a hearing decision by the contractor, the Board or the CMS reviewing official, as the case may be.

\* \* \* \* \*

■ 4. Section 405.1811 is amended by revising paragraphs (a)(2) and (c)(3) to read as follows:

#### § 405.1811 Right to contractor hearing; contents of, and adding issues to, hearing request.

(a) \* \* \*

(2) With the exception of an IOPO or histocompatibility laboratory, the amount in controversy (as determined in accordance with § 405.1839) must be at least \$1,000 but less than \$10,000. An IOPO or histocompatibility laboratory is subject to the amount in controversy requirement specified in § 413.420(g).

\* \* \* \* \*

(c) \* \* \*

(3) Unless the provider qualifies for a good cause extension under § 405.1813, the date of receipt by the contractor of the provider's hearing request must be no later than 180 days after the date of receipt by the provider of the final contractor or Secretary determination. An IOPO or histocompatibility laboratory is subject to the amount in controversy requirement specified in § 413.420(g).

\* \* \* \* \*

■ 5. Section 405.1813 is amended by revising paragraphs (e)(1) and (2) and adding paragraph (e)(3) to read as follows:

#### § 405.1813 Good cause extension of time limit for requesting a contractor hearing.

\* \* \* \* \*

(e) \* \* \*

(1) A decision denying an extension request under this section and dismissing the appeal is final and



binding on the provider, unless the dismissal decision is—

- (i) Reviewed by a CMS reviewing official in accordance with § 405.1834(b)(2)(i) of this subpart;
- (ii) Reviewed by the Administrator; or
- (iii) Reopened and revised by the contractor hearing officer(s) in accordance with §§ 405.1885 through 405.1889 of this subpart.

(2) The contractor hearing officer(s) promptly sends the decision to the appropriate component of CMS (currently the Center for Medicare) (as specified in § 405.1834(b)(4) of this subpart).

(3) A decision granting an extension request under this section is not subject to immediate review by a CMS reviewing official (as described in § 405.1834(b)(3) of this subpart). Any decision may be examined during—

- (i) The course of a CMS reviewing official's review of a final jurisdictional dismissal decision or a final hearing decision by the contractor hearing officer(s) (as described in § 405.1834(b)(2)(i) and (ii) of this subpart); or

(ii) The Administrator's review of a CMS reviewing official decision.  
■ 6. Section 405.1814 is amended by revising paragraphs (a)(5), (c)(3), and (d) to read as follows:

**§ 405.1814 Contractor hearing officer jurisdiction.**

(a) \* \* \*

(5) Final jurisdictional findings and jurisdictional dismissal decisions by the contractor hearing officer(s) are subject to the CMS reviewing official procedure in accordance with paragraph (d) of this section and § 405.1834(b)(2)(i) and (b)(2)(ii) of this subpart, as well as the possibility of review by the Administrator as described in § 405.1834(g).

\* \* \* \* \*

(c) \* \* \*

(3) A jurisdictional dismissal decision by the contractor hearing officer(s) under paragraph (c)(2) of this section is final and binding on the parties, unless the decision is—

- (i) Reviewed by a CMS reviewing official in accordance with § 405.1834 of this subpart;
- (ii) Is subsequently reviewed by the Administrator in accordance with § 405.1834 of this subpart; or
- (iii) Reopened and revised by the contractor hearing officer(s) in accordance with §§ 405.1885 through 405.1889 of this subpart.

(d) *CMS reviewing official and Administrator review of jurisdictional decisions.* Any finding by the contractor hearing officer as to whether it has

jurisdiction to grant a hearing on a specific matter at issue in an appeal is not subject to further administrative review, except as provided in this paragraph. The contractor hearing officer's jurisdictional findings as to specific matters at issue in an appeal may be reviewed solely during the course of the CMS reviewing official's review of one of the contractor hearing officer decisions specified in § 405.1834(b)(2) of this subpart or during the course of the Administrator's review of a CMS reviewing official's decision.

■ 7. Section 405.1821 is amended by revising paragraphs (d)(2) introductory text, (d)(2)(i), and (d)(2)(iii) introductory text to read as follows:

**§ 405.1821 Prehearing discovery and other proceedings prior to the contractor hearing.**

\* \* \* \* \*

(d) \* \* \*

(2) *Exception.* To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the contractor hearing officer(s), that portion of the discovery or disclosure ruling may immediately be reviewed by a CMS reviewing official or the Administrator in accordance with § 405.1834.

(i) Upon notice to the contractor hearing officer that the provider intends to seek immediate review of a ruling, or that the contractor or other affected nonparty intends to suggest that the CMS reviewing official or the Administrator, take own motion review of the ruling, the contractor hearing officer stays all proceedings affected by the ruling.

(iii) If the CMS reviewing official or the Administrator—

\* \* \* \* \*

■ 8. Section 405.1833 is revised to read as follows:

**§ 405.1833 Effect of contractor hearing decision.**

(a) A contractor hearing decision issued in accordance with § 405.1831 of this subpart is final and binding on all parties to the contractor hearing and on the contractor, unless the contractor hearing decision is—

- (1) Reviewed by a CMS reviewing official or by a CMS reviewing official and then is in turn reviewed by the Administrator in accordance with § 405.1834 of this subpart; or
- (2) Reopened and revised by the contractor hearing officer(s) in accordance with §§ 405.1885 through 405.1889 of this subpart.

(b) Final contractor hearing decisions are subject to the provisions of § 405.1803(d) of this subpart.

■ 9. Section 405.1834 is amended by—

- a. Revising the section heading and paragraphs (a), (b)(1)(ii), (b)(4) introductory text, (b)(4)(ii), (c), (c)(1)(i), (c)(3), (c)(3)(i), (d), (d)(1);
- b. Adding paragraphs (d)(4) and (d)(5);
- a. Revising paragraphs (e)(1), (e)(3), (f) introductory text, (f)(1) and (f)(2) introductory text;
- c. Adding paragraphs (f)(3) and (g).

The revisions and additions read as follows:

**§ 405.1834 CMS reviewing official procedure and Administrator review.**

(a) *Scope.* CMS or a provider that is a party to, and dissatisfied with, a final decision by the contractor hearing officer(s), upon submitting a request that meets the requirements of paragraph (c) of this section, is entitled to further administrative review of the decision by a CMS reviewing official, and the decision may be reviewed at the discretion of first a designated CMS reviewing official and discretionary review by the Administrator. No other individual, entity, or party has the right to the review. The review is conducted first by a designated CMS reviewing official who considers whether the decision of the contractor hearing officer(s) is consistent with the controlling legal authority (as described in § 405.1834(e)(1) of this subpart) and the evidence in the record, and the CMS reviewing official's decision may then be subject to further discretionary review by the Administrator.

(b) \* \* \*

(1) \* \* \*

(ii) The CMS reviewing official exercises this review authority in response to a request from a provider party to the appeal that meets the requirements of paragraph (c) of this section, or in response to a request from CMS, or may exercise his or her discretion to take own motion review.

\* \* \* \* \*

(4) The contractor hearing officer(s) must promptly send copies of any decision specified in paragraph (b)(2) or (b)(3) of this section or in § 405.1821(d)(2) of this subpart and the underlying contractor hearing officer's administrative record to the appropriate component of CMS (currently the Center for Medicare).

(i) \* \* \*

(ii) The appropriate CMS component examines each contractor hearing officer decision that is reviewable under paragraph (b)(2) or (b)(3) of this section or § 405.1821(d)(2) of this subpart, along with any review requests and any other

submissions made by a party or CMS in accordance with the provisions of this section, in order to assist the CMS reviewing official's and the Administrator's exercise of this review authority.

(c) *Request for review by a CMS reviewing official.*

(1) \* \* \*

(i) The date of receipt by the appropriate CMS component of the review request is no later than 60 days after the date of receipt by the provider of the contractor hearing officer decision; and

\* \* \* \* \*

(3) A request from a party or CMS for immediate review of a contractor hearing officer ruling authorizing discovery or disclosure in accordance with paragraph (b)(3) of this section must—

(i) Be made as soon as practicable after the ruling is made, but in no event later than 5 business days after the date the requesting party or CMS received notice of the ruling; and

\* \* \* \* \*

(d) *Own motion review of a CMS reviewing official.*

(1) The CMS reviewing official has discretion to take own motion review of a contractor hearing officer decision (regardless in either case of whether the decision was favorable or unfavorable to the provider) or other reviewable action.

\* \* \* \* \*

(4) If the CMS reviewing official does not notify the parties and the contractor that he or she intends to review the contractor hearing officer decision or other reviewable action within 90 days after the date of the contractor hearing officer's decision, then the Administrator may issue a notice instructing the CMS reviewing official to review the contractor hearing officer decision and issue a decision if the CMS reviewing official fails to do so.

(i) The Administrator promptly provides copies of the notice instructing the CMS reviewing official to review the contractor hearing officer decision to the parties, the contractor, and to the appropriate component of CMS.

(ii) After the CMS reviewing official's receipt of the Administrator's notice (instructing the CMS reviewing official to review the contractor hearing officer decision and issue a decision), the CMS reviewing official must allow the parties a reasonable period to comment on the issues identified by the Administrator for review.

(5) If no party requests review of the contractor hearing decision and the CMS reviewing official does not take review on his or her own motion or at

the direction of the Administrator within the time periods specified in this paragraph, the contractor hearing officer decision is final in accordance with § 405.1833 of this subpart.

(e) \* \* \*

(1) In reviewing a contractor hearing officer decision specified in paragraph (b)(2) or (b)(3) of this section, the CMS reviewing official must—

\* \* \* \* \*

(3) Upon completion of the review of a contractor hearing decision specified in paragraph (b)(2) or (b)(3) of this section, the CMS reviewing official issues a written decision that includes findings of fact and conclusions of law on jurisdictional issues and on the merits of each issue under review over which the CMS reviewing official has jurisdiction and affirms, reverses, or modifies the contractor hearing decision or remands the contractor hearing decision to the contractor hearing officer for further proceedings. A copy of the decision must be sent promptly to each party, to the contractor, and to the appropriate component of CMS (currently the Center for Medicare).

(f) *Effect of a reviewing official's decision, remand, and the possibility of Administrator review.*

(1) A decision of affirmation, reversal, or modification by the CMS reviewing official is final and binding on each party and the contractor, except as set forth in paragraph (g) of this section. The CMS reviewing official's decision may be reopened and revised by the CMS reviewing official in accordance with §§ 405.1885 through 405.1889 of this subpart. Decisions of a CMS reviewing official are subject to the provisions of § 405.1803(d) of this subpart. A decision by a CMS reviewing official remanding an appeal to the contractor hearing officer(s) for further proceedings under paragraph (f)(2) of this section is not a final decision.

(2) A remand to the contractor hearing officer(s) by the CMS reviewing official must do all of the following:

\* \* \* \* \*

(3) The CMS reviewing official must promptly send copies of the CMS reviewing official decision, along with any other submissions made by a party or CMS in accordance with the provisions of this section, to the appropriate component of CMS (currently the Center for Medicare) and to the Administrator c/o the CMS Office of the Attorney Advisor.

(g) *Administrator review of a CMS reviewing official's decision.*

(1) CMS or any party to a CMS reviewing official decision may request Administrator review of a CMS

reviewing official decision in accordance with this section. No other provider, individual, or entity may request review. The Administrator may grant or deny review of a CMS reviewing official decision at his or her discretion. The Administrator may also review any decision of the CMS reviewing official on his or her own motion (regardless of whether the decision was favorable or unfavorable to the provider).

(2) A party or CMS may request that the Administrator review a CMS reviewing official decision within 15 days of their receipt of a final CMS reviewing official decision.

(i) All requests for Administrator review and any other submissions to the Administrator under this paragraph must be sent to the Office of the Attorney Advisor. The request for review must be in writing, attach a copy of the CMS reviewing official decision for which it seeks review, and include a brief description of all of the following:

(A) Those aspects of the CMS reviewing official decision with which the requestor is dissatisfied.

(B) The reasons for the requestor's dissatisfaction.

(C) Any argument or record evidence the requestor believes supports its position.

(D) Any additional, extra-record evidence relied on by the provider, along with a demonstration that such evidence was improperly excluded in proceedings below (as described in § 405.1823 of this subpart).

(ii) The Administrator must issue a Notice advising the parties of his or her intent to review or to decline to review within 30 days of the Administrator's receipt of a request for review from CMS or any party to the CMS reviewing official's decision. That Notice must be promptly sent to the parties, the contractor, and the appropriate component of CMS. A Notice advising the parties of the Administrator's intent to review must contain a brief statement of the issues under "review and solicit comments from the parties, the contractor, and CMS. A Notice that the Administrator is declining to review need not set forth the basis for the Administrator's decision to decline review the CMS reviewing official's decision.

(iii) If the Administrator declines to review the reviewing official decision or the Administrator does not issue a determination regarding review of the reviewing official decision within 30 days of the Administrator's receipt of a request to review, the decision of the CMS reviewing official is final. Upon

issuance of a Notice, within 30 days of a request for Administrator review of a CMS reviewing official decision, that the Administrator is declining to review the reviewing official's decision, the CMS reviewing official's decision becomes final in accordance with paragraph (f)(1) of this section.

(3) Within 45 days of the Administrator's receipt of a CMS reviewing official's decision, the Administrator may issue a Notice of Review on his or her own motion. The Notice of Review must be sent to the parties, the contractor, and the appropriate component of CMS. The Notice of Review must contain a brief statement of the issues under review and solicit comments from the parties, contractor, and CMS. If the Administrator does not issue a determination regarding his or her own motion review within 45 days of the Administrator's receipt of a CMS reviewing official's decision, the decision of the CMS reviewing official is final.

(4) If the Administrator elects to review the CMS reviewing official's decision—

(i) The Administrator will set deadlines for the parties and affected nonparties to submit comments; and

(ii) The Administrator's decision affirming, reversing, or modifying the CMS reviewing official's decision is final and binding on each party and the contractor. A decision remanding an appeal to the CMS reviewing official, contractor hearing officer(s) is not a final decision. Decisions of the Administrator are subject to the provisions of § 405.1803(d) of this subpart.

(5) If the Administrator does not issue a written decision that affirms, reverses, modifies or remands the CMS reviewing official's decision within 60 days of the date of issuance of the Notice of Review, the CMS reviewing official's decision becomes final in accordance with paragraph (f)(1) of this section.

(6) The Administrator may remand the CMS reviewing official's decision to the CMS reviewing official, to the contractor hearing officer, or to the contractor. A remand by the Administrator must do all of the following:

(i) Vacate the CMS reviewing official's and/or the contractor hearing officer decisions as to the specific issues remanded.

(ii) Be governed by the same criteria that apply to remands by the Administrator to the Board under § 405.1875(f)(2) of this subpart, and require the entity to which the matter is

remanded to take specific actions on remand.

(iii) Result in the CMS reviewing official, contractor hearing officer(s), or contractor taking the actions required on remand and issuing a new decision.

#### **PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES**

■ 9. The authority citation for part 412 continues to read as follows:

**Authority:** 42 U.S.C. 1302 and 1395hh.

■ 10. Section 412.24 is amended by adding paragraph (g) to read as follows:

##### **§ 412.24 Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.**

\* \* \* \* \*

(g) *Requirements for submission of electronic clinical quality measures (eCQMs) under the PCHQR Program.*

When reporting eCQMs under the PCHQR Program, PCHs must use all of the following:

(1) Health information technology (IT) certified to the ONC Health IT Certification Program certification criteria necessary for eCQM reporting, as adopted and updated at 45 CFR 170.315(c).

(2) Certified health IT described in paragraph (g)(1) to calculate, export, and submit results for the eCQMs available to report under the PCHQR Program.

(3) The eCQM electronic measure specifications for the applicable reporting period available on the Electronic Clinical Quality Improvement Resource Center website at <https://ecqi.healthit.gov/> or another website as designated by CMS.

■ 11. Section 412.87 is amended by revising paragraphs (c) introductory text, (d), and (f) to read as follows:

##### **§ 412.87 Additional payment for new medical services and technologies: General provisions.**

\* \* \* \* \*

(c) *Eligibility criteria for alternative pathway for certain transformative new devices.* For applications submitted for new technology add-on payments for FYs 2021 through 2027, inclusive, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical devices, if the following conditions are met:

\* \* \* \* \*

(d) *Eligibility criteria for alternative pathway for certain antimicrobial products.* For applications submitted for new technology add-on payments for

FYs 2021 through 2027, inclusive, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical products, if the following conditions are met:

(1)(i) For applications submitted for new technology add-on payments for FYs 2021 through 2027, inclusive, a new medical product is designated by FDA as a Qualified Infectious Disease Product and has received marketing authorization for the indication covered by the Qualified Infectious Disease Product designation; or

(ii) For applications submitted for new technology add-on payments for FYs 2022 through 2027, inclusive, a new medical product is approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway.

\* \* \* \* \*

(f) *Announcement of determinations and deadline for consideration of new medical service or technology applications.*

(1)(i) CMS considers whether a new medical service or technology meets the eligibility criteria specified in paragraph (b) of this section and announces the results in the **Federal Register** as part of its annual updates and changes to the IPPS.

(ii) CMS only considers any particular new medical service or technology for add-on payments under paragraph (b) of this section.

(2) CMS only considers, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA marketing authorization by May 1 prior to the particular fiscal year.

##### **§ 412.88 [Amended]**

■ 12. Section 412.88 is amended in paragraph (a)(2)(ii)(A) introductory text by removing the phrase "paragraph (a)(2)(ii)(B) of" and adding in its place the phrase "paragraphs (a)(2)(ii)(B) and (C) of".

##### **§ 412.90 [Amended]**

■ 13. Section 412.90 paragraph (j) is amended by removing the date "October 1, 2025" and adding in its place the date "January 1, 2027".

##### **§ 412.101 [Amended]**

■ 14. Section 412.101 is amended by—  
■ a. In paragraph (b)(2)(i), removing the phrase "FY 2010 and FY 2026 and subsequent years," and adding in its place the phrase "FY 2010 and the portion of FY 2027 beginning January 1, 2027, and subsequent fiscal years,";

- b. In paragraph (b)(2)(iii), removing the phrase “FY 2025,” and adding in its place the phrase “the portion of FY 2027 ending December 31, 2026,”;
  - c. In paragraph (c)(1), removing the phrase “FY 2010 and FY 2026 and subsequent years,” and adding in its place the phrase “FY 2010 and the portion of FY 2027 beginning January 1, 2027, and subsequent fiscal years,”; and
  - d. In paragraph (c)(3) introductory text, removing the phrase “FY 2019 through FY 2025,” and adding in its place “FY 2019 through the portion of FY 2027 ending December 31, 2026,”.
- 15. Section 412.105 is amended by revising paragraph (f)(1)(i) to read as follows:

**§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.**

\* \* \* \* \*

- (f) \* \* \*
- (1) \* \* \*

(i) The resident must be enrolled in an approved teaching program. An approved teaching program is one that meets one of the following requirements, subject to the requirements in § 413.84 of this chapter:

(A) Is approved by one of the national organizations listed in § 415.152 of this chapter.

(B) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(1) The Directory of Graduate Medical Education Programs published by the American Medical Association.

(2) The Annual Report and Reference Handbook published by the American Board of Medical Specialties.

(C) Is approved by the Accreditation Council for Graduate Medical Education (ACGME), or other organization designated by the Secretary, as a fellowship program in geriatric medicine.

**§ 412.108 [Amended]**

- 16. Section 412.108 is amended by—

- a. In paragraph (a)(1) introductory text, removing the date “October 1, 2025” and adding in its place the date “January 1, 2027”; and

- b. In paragraph (c)(2)(iii) introductory text, removing the date “October 1, 2025” and adding in its place the date “January 1, 2027”.

**§ 412.116 [Amended]**

- 17. Section 412.116 is amended in paragraph (c) by removing the phrase “for kidney acquisition costs in hospitals with approved kidney transplant programs)” and adding in its place the phrase “for organ acquisition

costs in hospitals with approved organ transplant programs)”.

- 18. Section 412.230 is amended by—

- a. In paragraph (a)(5)(i) removing the phrase “purposes of the wage index if the pre-reclassified” and adding in its place the phrase “purposes of the wage index if, using data described in paragraph (d)(2) of this section, the pre-reclassified”;

- b. Revising paragraph (c)(1); and

- c. Adding paragraph (d)(6).

The revision and addition read as follows:

**§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.**

\* \* \* \* \*

- (c) \* \* \*

(1) To demonstrate proximity to the area, the hospital must submit evidence from a nationally recognized electronic mapping service of the shortest route from the front entrance of the hospital over improved roads or waterways traveled by ferry boats to the county line of the requested area and the distance of that route.

\* \* \* \* \*

- (d) \* \* \*

(6) *Home area reclassification exception.* The requirements of paragraph (d)(1)(iv) of this section do not apply to a hospital that has been granted redesignation as rural under § 412.103 and seeks redesignation under this section to its geographic urban area.

**PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES**

- 19. The authority citation for part 413 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

- 20. Section 413.5 is amended by adding paragraphs (c)(10) through (c)(19) to read as follows:

**§ 413.5 Cost reimbursement: General.**

\* \* \* \* \*

- (c) \* \* \*

(10) Costs incurred by providers for entertainment, including costs associated with entertainment activities, or that are entertainment in nature, are not allowable costs.

(i) This paragraph (c)(10) includes costs that OPOs incur to engage in public education to increase awareness

of organ donation and increase donor registration.

(ii) Non-allowable entertainment costs include, but are not limited to the following:

(A) Tickets, admission fees, or entry to sporting or other events, including national or professional sporting events.

(B) Sponsorship of sporting events, teams or athletes, including race car drivers or motorsports activities.

(C) Sponsorship of floats in national parades.

(D) Concert, theater, or performing arts events, professional musicians or other entertainers.

(E) Wine tours or alcoholic beverages.

(F) Retreats held at spas or luxury resorts, spa services or treatments.

(G) Golf outings, ski trips, cruises, and similar recreational excursions.

(11) Costs incurred by OPOs to engage in public education within its donation service area to increase awareness of organ donation and increase donor registration are allowable if they are reasonable and do not violate paragraph (c)(10) of this section.

(12) Costs incurred by providers for anyone for purposes of employee and non-employee entertainment activities and employee morale which include, but are not limited to, picnics, parties, performers, entertainment, award ceremonies or the sponsorship of scholarships or athletic programs are not allowable costs.

(13) Costs incurred by providers to furnish alcoholic beverages to anyone are not allowable costs.

(14) Costs incurred by OPOs—

(14) Costs incurred by OPOs—

(i) For professional education such as meetings, seminars, and presentations on organ donation to acquire all useable organs from potential donors where continuing education credits are not given and where the attendee is clinical staff such as OPO staff, donor hospital staff, and physicians are allowable costs; and

(ii) For OPO-sponsored seminars where continuing education credits are given and where the attendee is on the OPO staff are allowable costs to the extent that they are patient care related, reasonable and necessary; and

(iii) For OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO staff, in accordance with § 413.402(d)(2)(v) are not allowable costs.

(15) Costs incurred by providers—

(i) For employee travel are generally allowable to the extent that they are patient care related, reasonable and necessary. Costs for travel not related to patient care are not allowable costs;

(ii) To conduct, or send its employees or staff to, patient care related professional education refresher programs, seminars and workshops that increase the quality of patient care or operating efficiency of the provider, are generally allowable costs to the extent that they are patient care related, reasonable and necessary;

(iii) For entertainment and vacation travel expenses such as travel on cruises or to resorts or spas, or transportation to entertainment or sporting events, are not allowable costs regardless of whether they are or are not incurred in connection with professional educational seminars or continuing education; and

(iv) Related to the personal use of provider vehicles are not allowable costs.

(16) Costs incurred by providers—

(i) For meals sold to visitors, meals for their employees and staff (including executives and management) and non-personnel (including attending physicians) are not allowable costs.

(ii) For meals and refreshments provided to attendees at educational events, including attendees of OPO-sponsored seminars (with or without continuing education credits) are not allowable costs.

(17) Costs incurred by providers for drugs sold to other than patients are not related to patient care and are not allowable costs.

(18) Costs incurred by providers for cost of fines or penalties resulting from Federal, State or local laws are not allowable costs.

(19) Costs incurred by providers for operation of a gift shop are not allowable costs.

\* \* \* \* \*

■ 21. Section 413.9 is amended by adding paragraphs (b)(3) and (c)(4) to read as follows:

**§ 413.9 Cost related to patient care.**

\* \* \* \* \*

(b) \* \* \*

(3) *Prudent buyer.* The prudent buyer is a person, provider type or entity that purchases items or property with caution, good judgment, and a sensible approach, aiming to make a sound, informed decision that minimizes risk and avoids unnecessary financial loss. This person, provider type or entity thoughtfully evaluates the condition, legal, and financial aspects of a purchase, much like a reasonably prudent person would in a similar situation.

(c) \* \* \*

(4) Providers are expected to economize by not paying more than the going price for an item or service and

seeking to minimize their costs, so that their actual costs will not exceed what a prudent and cost-conscious buyer would pay for a given item or service. If costs are determined to exceed the level that prudent buyers incur, the excess costs are not reimbursable in the absence of clear evidence that the higher costs were unavoidable.

■ 22. Section 413.24 is amended by adding paragraph (d)(8) to read as follows:

**§ 413.24 Adequate cost data and cost finding.**

\* \* \* \* \*

(d) \* \* \*

(8) *Improper allocation of overhead prohibited.* Providers must not include a statistical cost which does not relate to the allocation of administrative and general expenses when it causes an improper distribution of overhead.

(i) Providers must employ either or both methods described in paragraphs (d)(8)(ii) or (iii) of this section, if needed, to prevent the improper allocation of overhead on the Medicare cost report.

(ii) *Negative Adjustment Method for accumulated cost.* When direct costs are reported in a cost center or department that includes purchased services or supplies, costs other than the purchased service costs may receive an allocation of administrative and general costs, and the purchased service costs that are not to receive administrative and general must be identified and removed.

(A) On the Medicare cost report, in any column using accumulated costs as the statistical basis for allocating costs, providers must identify any cost center that is not to receive an allocation by entering a negative 1 (-1) on the appropriate line in the accumulated cost column, or by entering the total accumulated cost as a negative amount on the appropriate line in the reconciliation column. For those cost centers using accumulated costs that are to receive partial allocation of costs, providers must enter a negative amount for the costs that are to be excluded from the statistic on the appropriate line in the reconciliation column.

(B) Cost centers that are not to receive an allocation must not have entries in both the reconciliation and accumulated cost columns when the accumulated cost statistic is offset to zero.

(C) For those cost centers that are to receive partial allocation of costs for costs other than purchased services, the cost to be excluded from the accumulated cost statistic must be reported as a negative amount on the effected cost center in the reconciliation column. This results in entries in both

the reconciliation column and accumulated cost statistic column simultaneously for the same line (cost center).

(iii) *Fragmenting (componentizing): Administrative and General Method.*

When a provider chooses to fragment, or componentize administrative and general costs, the provider must fragment (that is, subscript), the administrative and general cost center into 2 or more cost centers using accurate statistics to allocate its costs and ensure that overhead costs are accurately assigned to departments benefiting from the services provided. When creating multiple administrative and general cost centers, a provider must track and allocate overhead expenses based on actual resource consumption.

(iv) *Provider request to change its cost finding method.*

(A) A provider that wishes to change its cost finding method must submit a request to its contractor, in writing, 90 days prior to the end of the cost reporting period to which the provider's request for change applies.

(B) The contractor's determination of a provider's request to change methods will be furnished to the provider in writing and will be binding on the provider as of the date of the contractor's written notice.

(C) When the contractor approves the provider's request to change methods, the provider must use this method for the cost reporting period to which the request applies and for all subsequent cost reporting periods, unless the contractor approves a subsequent request by the provider to change its cost finding methods.

\* \* \* \* \*

**§ 413.65 [Amended]**

■ 23. Section 413.65 is amended by:

■ a. In paragraph (e)(3)(iii)(A) removing the phrase "the facility or organization" and adding in its place the phrase "an inpatient or outpatient facility or organization"; and

■ b. In paragraph (e)(3)(iii)(B) removing the phrase "the facility or organization" and adding in its place the phrase "an outpatient facility or organization".

■ 24. Section 413.75 is amended in paragraph (b) by revising the definitions for "Approved geriatric program" and "Approved medical residency program" to read as follows:

**§ 413.75 Direct GME payments: General requirements.**

\* \* \* \* \*

(b) \* \* \*

\* \* \* \* \*

*Approved geriatric program* means, subject to the requirements in § 413.84 of this chapter, a fellowship program of one or more years in length that is approved by one of the national organizations listed in § 415.152 of this chapter under that respective organization's criteria for geriatric fellowship programs.

*Approved medical residency program* means, subject to the requirements in § 413.84 of this chapter, a program that meets one of the following criteria:

(i) Is approved by one of the national organizations listed in § 415.152 of this chapter.

(ii) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(A) The Directory of Graduate Medical Education Programs published by the American Medical Association, and available from American Medical Association, Department of Directories and Publications, 515 North State Street, Chicago, Illinois 60610.

(B) The Annual Report and Reference Handbook published by the American Board of Medical Specialties, and available from American Board of Medical Specialties, One Rotary Center, Suite 805, Evanston, Illinois 60201.

(iii) Is approved by the Accreditation Council for Graduate Medical Education (ACGME), or other organization designated by the Secretary, as a fellowship program in geriatric medicine.

\* \* \* \* \*

■ 25. Section 413.79 is amended by revising paragraph (l) to read as follows:

**§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.**

\* \* \* \* \*

(l) For purposes of this section, a new medical residency training program means a program that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995, and that meets the following conditions:

(1) Subject to the provisions of paragraphs (l)(2) and (l)(3) of this section, effective for programs started on or after October 1, 2026, at least 90 percent of the individual residents that participate in the program during the 5-year cap building period (that is, for new urban teaching hospitals, during the first 5 program years of the first new program's existence under paragraph (e)(1) of this section; and for rural hospitals, during the first 5 program years of each new program under paragraph (e)(3) of this section) must not

have previous experience training in another program in the same specialty.

(2) For purposes of determining whether a program satisfies the requirement under paragraph (l)(1) of this section, the count of individual residents excludes an individual—

(i) With previous experience training in another program in the same specialty who enters the program as a first-year resident through the National Resident Matching Program or another binding third-party resident matching program; or

(ii) Who meets the definition of a “displaced resident” under paragraph (h)(1)(iii) of this section.

(3) The requirement under paragraph (l)(1) of this section does not apply to a program accredited for 16 or fewer resident positions.

\* \* \* \* \*

■ 26. Section 413.84 is added to read as follows:

**§ 413.84 Prohibition against unlawful discrimination.**

(a) An approved medical residency training program, as defined in §§ 412.105(f)(1)(i), 413.75(b), and 415.152 of this chapter, or an approved nursing and allied health education program, as defined in § 413.85 of this chapter, must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits.

(b) An accrediting organization of approved medical residency training programs under §§ 412.105(f)(1)(i), 413.75(b), and 415.152 of this chapter, or of approved nursing and allied health education programs under § 413.85 of this chapter, and any publications cited in the regulations that list specialties or subspecialties of such programs, must not use criteria that discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits.

(c) Approved medical residency training programs and approved nursing and allied health education programs include programs that would be accredited except for the accrediting

agency's reliance upon an accreditation standard that requires an entity to—

(1) Discriminate, or promote or encourage discrimination, on the basis of race, color, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits; or

(2) Perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether the standard provides exceptions or exemptions.

■ 27. Section 413.85 is amended by—

■ a. In paragraph (c), revising the definition of “Approved educational activities” introductory text; and

■ b. Revising paragraphs (d)(2) and (e).

The revisions read as follows:

**§ 413.85 Cost of approved nursing and allied health education activities.**

\* \* \* \* \*

(c) \* \* \*

*Approved educational activities* means, subject to the requirements in § 413.84 of this chapter, formally organized or planned programs of study of the type that—

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(i) Subject to the provisions of paragraphs (d)(2)(ii) and (iii) of this section, the net cost of approved educational activities is determined as follows:

(A) Determine allowable direct costs incurred by the provider for trainee stipends and compensation of faculty employed by the provider.

(B) Subtract from those direct costs the revenues the provider receives from students or on behalf of students enrolled in the program, such as, but not limited to, tuition, student fees, or textbooks purchased for resale.

(C) Allocate indirect costs of the activities as determined under the Medicare cost-finding principles in § 413.24, limited to those costs that the provider itself incurs as a consequence of operating the approved educational activities.

(ii) The direct and indirect allowable costs of educational activities do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support.

\* \* \* \* \*

(e) *Approved nursing and allied health education programs.* Subject to the requirements in § 413.84 of this chapter, CMS will consider an activity an approved nursing and allied health education program if the program is a planned program of study that is licensed by State law, or if licensing is not required, is accredited by the recognized national professional organization for the particular activity.

\* \* \* \* \*

■ 28. Section 413.402 is amended by revising paragraph (a) and (d)(2)(v) to read as follows:

**§ 413.402 Organ acquisition costs.**

(a) *Costs related to organ acquisition.* Costs recognized in paragraph (b) of this section are allowable costs incurred in the acquisition of organs intended for transplant, including those organs that are subsequently determined unsuitable for transplant and furnished for research from a living donor or a deceased donor by the hospital, or from a deceased donor by an OPO. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or a TH. Costs incurred by OPOs for public education within its donation service area in accordance with § 413.5(c)(11) and professional education in accordance with § 413.5(c)(14)(iii) are allowable overhead costs and are included on the cost report for an OPO.

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(v) Costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at § 486.326(b)). Costs incurred by OPOs for public education within their donation service area in accordance with § 413.5(c)(11) and professional education in accordance with § 413.5(c)(14)(iii) are allowable overhead costs.

\* \* \* \* \*

■ 29. Section 413.404 is amended by—

■ a. In paragraph (b)(3)(ii)(A) removing the phrase “average cost” and adding in its place the phrase “average organ acquisition cost”;

■ b. Adding paragraph (b)(3)(ii)(C)(8);

■ c. Revising paragraph (c) introductory text; and

■ d. Adding paragraph (d);

The additions and revision read as follows:

**§ 413.404 Standard acquisition charge.**

\* \* \* \* \*

(b) \* \* \*

(3) \* \* \*

(ii) \* \* \*

(C) \* \* \*

(8) Registry fees as specified in § 413.402(b)(6) of this subpart.

(c) *Independent OPO SACs, for cost reporting periods beginning before October 1, 2027—*

\* \* \* \* \*

(d) *Independent OPO organ SACs, for cost reporting periods beginning on or after October 1, 2027—*

(1) *General.* For each organ type, the contractor establishes the organ-specific SAC based on an estimate of initial year projected or subsequent years' actual, reasonable and necessary costs that the IOPO expects to incur to procure deceased donor organs during the IOPO's cost reporting period, divided by the initial year projected or subsequent years' actual, number of usable deceased donor organs the IOPO expects to procure.

(i) *Initial year.* For each organ type, the contractor develops the IOPO's initial organ-specific SAC, based on the IOPO's budget information.

(ii) *Subsequent years.* For each organ type, the contractor computes the organ-specific SAC for subsequent years using the IOPO's costs related to organ acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable deceased donor organs procured during that cost reporting period.

(iii) *Relationship to interim payments.* Each organ-specific SAC amount is the organ-specific interim payment the TH or other OPO pays to the IOPO, as set forth in § 413.420(d)(2)(i) and (ii).

(iv) *Costs to develop the IOPO deceased donor SACs.* Costs that may be used to develop the IOPO deceased donor SACs include, but are not limited to the following:

(A) Costs of organs acquired from other THs or OPOs.

(B) Costs of transportation as specified in § 413.402(b)(8).

(C) Surgeons' fees for excising deceased donor organs (limited to \$1,250 for kidneys).

(D) Costs of tissue typing services, including those furnished by independent laboratories.

(E) Organ preservation and perfusion costs.

(F) General routine and special care service costs (for example, intensive care unit or critical care unit services related to the donor).

(G) Operating room and other inpatient ancillary service costs.

(v) *SAC adjustments.* Only the contractor may adjust the organ SACs. IOPOs may request that the contractor

make an adjustment in accordance with § 413.64(e), or the contractor may initiate an adjustment, in accordance with § 413.64(d)(2) or § 413.64(e), as applicable.

(2) *Billing SACs for organs generally.* When an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses its SAC for each organ type, and not the procuring IOPO's SAC, when billing the TH receiving the organ.

■ 30. Section 413.420 is amended by—

■ a. Revising the section heading and paragraphs (a), (c) introductory text, (c)(1) introductory text, (c)(1)(ii) and (iv);

■ b. In paragraph (c)(2), removing the phrase “IOPO or laboratory” and adding in its place the phrase “IOPO or HCL”;

■ c. Revising paragraph (d);

■ d. In paragraph (e)(1) introductory text removing the phrase “IOPOs and histocompatibility laboratories” and adding in its place the phrase “IOPOs and HCLs”;

■ e. In paragraph (e)(1)(i) removing the phrase “IOPO or laboratory” and adding in its place the phrase “IOPO or HCL”;

■ f. In paragraph (e)(2) introductory text removing the phrase “IOPO or histocompatibility laboratory” and adding in its place the phrase “IOPO or HCL”;

■ g. Revising paragraphs (e)(2)(i) and (ii);

■ h. Adding paragraph (e)(3); and

■ i. Revising paragraph (g).

The revisions and additions read as follows:

**§ 413.420 Payment to independent organ procurement organizations (IOPOs) and histocompatibility laboratories (HCLs) for organ acquisition costs.**

(a) \* \* \*

(1) Covered services furnished by IOPOs and HCLs in connection with organ acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part as follows:

(i) For kidney acquisition and transplantation services, IOPOs and HCLs are reimbursed under the principles for determining reasonable cost.

(ii) For non-renal organ acquisition and transplantation services furnished for cost reporting periods beginning on or after October 1, 2027, IOPOs and HCLs are reimbursed under the principles for determining reasonable cost.

(2) Services furnished by IOPOs and HCLs, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by



the TH or OPO using a kidney SAC (for an IOPO) or contractor-established rates (for an HCL). (The reasonable costs of services furnished by IOPOs or HCLs are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

\* \* \* \* \*

(c) Agreements with IOPOs and HCLs.

(1) Any IOPO or HCL that wishes to have the cost of its pre-transplant services reimbursed under the Medicare program must file an agreement with CMS under which the IOPO or HCL agrees to do all of the following:

\* \* \* \* \*

(ii) To permit CMS to designate a contractor to determine the interim reimbursement rate, payable by the THs or OPOs for services provided by the IOPO or HCL, and to determine Medicare's reasonable cost based upon the cost report filed by the IOPO or HCL.

\* \* \* \* \*

(iv) To pay to CMS amounts that have been received or are receivable by IOPOs or HCLs from THs and OPOs, and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or HCL.

\* \* \* \* \*

(d) \* \* \*

(1) THs with approved transplant programs and OPOs pay the IOPO or HCL for their pre-transplantation services on the basis of interim rates established by the contractor for that IOPO or HCL, as follows:

(i) THs with approved kidney transplant programs and OPOs pay the IOPO or HCL for their kidney pre-transplantation services, based on interim rates established by the contractor for that IOPO or HCL.

(ii) THs with approved non-renal transplant programs and OPOs pay the IOPO or HCL for their non-renal organ pre-transplantation services furnished for cost reporting periods beginning on or after October 1, 2027, based on interim rates established by the contractor for that IOPO or HCL.

(2) The interim rates are contractor established rates, based on costs associated with procuring an organ for transplantation incurred by an IOPO or HCL, respectively, during its previous fiscal year, as follows:

(i) The interim rates for kidneys are a contractor established kidney SAC or contractor established rates, based on costs associated with procuring kidneys for transplantation, incurred by an IOPO or HCL, respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it

according to the IOPO's or HCL's estimate of its projected costs for the fiscal year.

(ii) For services furnished for cost reporting periods beginning on or after October 1, 2027, the interim rates for non-renal organs are contractor established non-renal organ-specific SACs or contractor established rates, based on costs associated with procuring each specific type of non-renal organ for transplantation incurred by an IOPO or HCL, respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rates, the contractor determines them according to the IOPO's or HCL's estimate of its projected costs for the fiscal year.

(3) Payments or amounts payable from THs and OPOs based on interim rates specified in paragraph (d)(2)(i) of this section are reconciled directly with the IOPO or HCL after the close of the IOPO's or HCL's fiscal year in accordance with § 413.420(e). For cost reporting periods beginning on or after October 1, 2027, payments or amounts payable from THs and OPOs based on interim rates specified in paragraph (d)(2)(ii) of this section are reconciled directly with the IOPO or HCL after the close of the IOPO's or HCL's fiscal year in accordance with § 413.420(e).

(4) When a contractor establishes interim rates for IOPOs and HCLs, it must disseminate those interim rates to all THs, OPOs, and contractors.

(e) \* \* \*

(2) \* \* \*

(i) *Retroactive adjustment.* A retroactive adjustment of the amounts received or receivable by the IOPO or HCL under the kidney interim rate is made in accordance with § 413.64(f).

(ii) *Lump sum adjustment.* If the determination of reasonable cost reveals an overpayment or underpayment resulting from the kidney interim reimbursement rate received or receivable by the IOPO or HCL from THs and OPOs, a lump sum adjustment is made directly between the contractor and the IOPO or HCL.

(3) *Audit and adjustment for cost reporting periods beginning on or after October 1, 2027.* A cost report submitted by an IOPO or HCL is reviewed by the contractor and new interim reimbursement rates for non-renal organ acquisition costs for the subsequent fiscal year are established by the contractor based upon this review.

(i) *Retroactive adjustment.* A retroactive adjustment of the amounts received or receivable by the IOPO or HCL under the non-renal organ-specific interim rates is made in accordance with § 413.64(f).

(ii) *Lump sum adjustment.* If the determination of reasonable cost reveals an overpayment or underpayment resulting from the non-renal organ-specific interim reimbursement rates received or receivable by the IOPO or HCL from THs and OPOs, a lump sum adjustment is made directly between the contractor and the IOPO or HCL.

\* \* \* \* \*

(g) *Appeals.* If the amount in controversy is \$1,000 or more, any IOPO or HCL that disagrees with a contractor's cost determination under this section is entitled to a contractor hearing, review of the contractor hearing officer's decision by a CMS reviewing official, and Administrator Review of a CMS reviewing official's decision, in accordance with the procedures set forth in §§ 405.1801(b)(2) and 405.1811 through 405.1834 of this chapter.

#### **PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS**

■ 31. The authority citation for part 415 continues to read as follows:

**Authority:** 42 U.S.C. 1302 and 1395h(h).

■ 32. Section 415.152 is amended in the definition of "Approved graduate medical education (GME) program" by revising the introductory text and paragraph (1) to read as follows:

#### **§ 415.152 Definitions.**

\* \* \* \* \*

*Approved graduate medical education (GME) program* means, subject to the requirements in § 413.84 of this chapter, one of the following:

(1) A residency program approved by the Accreditation Council for Graduate Medical Education, by the American Osteopathic Association, by the Commission on Dental Accreditation of the American Dental Association, or by the Council on Podiatric Medical Education of the American Podiatric Medical Association, or other organization determined by the Secretary.

\* \* \* \* \*

#### **PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES**

■ 33. The authority citation for part 419 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 34. Section 419.66 is amended by revising paragraph (c)(2)(ii) to read as follows:



#### § 419.66 Transitional pass-through payments: Medical devices.

(c) \* \* \*

(2) \* \* \*

(ii) For devices for which pass-through payment status began on or after January 1, 2020, and on or before January 1, 2028 for applications received through September 30, 2026, as an alternative pathway to paragraph (c)(2)(i) of this section, a new device is part of the Food and Drug Administration's (FDA's) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

#### PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 34. The authority citation for part 495 continues to read as follows:

**Authority:** 42 U.S.C. 1302 and 1395hh.

■ 35. Section 495.4 is amended in the definition of “Certified electronic health record technology (CEHRT)” by revising paragraphs (2)(i) and (2)(ii)(A) in introductory text to read as follows:

#### § 495.4 Definitions.

*Certified electronic health record technology (CEHRT)* \* \* \*

(2) \* \* \*

(i) For 2019 through 2026, at 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) \* \* \*

(A) For 2019 through 2026, the applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

\* \* \* \* \*

#### § 495.40 [Amended]

■ 36. Section 495.40 is amended in paragraph (b)(2)(i)(I) introductory text by removing the phrase “To engage” and adding in its place the phrase “Through CY 2026, to engage”.

#### PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR CERTAIN MODELS

■ 37. The authority citation for part 512 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1315a, and 1395hh.

■ 38. Section 512.505 is amended by—

■ a. Adding definitions for “APC update factor” and “MS-DRG update factor” in alphabetical order;

■ b. Revising definition for “Spinal fusion”; and

■ c. Adding definition for “Updated prospective trend factor” in alphabetical order.

The additions and revision read as follows:

#### § 512.505 Definitions.

\* \* \* \* \*

*APC update factor* refers to a component applied to the prospective trend factor to ensure that the APC weights corresponding to the performance year are incorporated into the target price calculations, as set forth in § 512.540(b)(7).

\* \* \* \* \*

*MS-DRG update factor* refers to a component applied to the prospective trend factor for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of the performance year to account for changes in MS-DRG definitions and weights between the first and second fiscal years in the performance year, as set forth in § 512.540(b)(7).

\* \* \* \* \*

*Spinal fusion* means any cervical, thoracic, or lumbar spinal fusion procedure paid through either of the following:

(1) The IPPS under—

(i) MS-DRG 402, 426, 427, 428, 429, 430, 447, 448, 450, 451, 471, 472, 473; and

(ii) On or after October 1, 2026 MS-DRG 523, 524, 525.

(2) The OPPS under HCPCS codes 22551, 22554, 22612, 22630, or 22633.

\* \* \* \* \*

*Updated prospective trend factor* refers to the multiplier incorporated into the preliminary target price to estimate changes in spending patterns between the baseline period and the corresponding calendar year and fiscal year in the performance year, calculated as set forth in § 512.540(b)(7).

\* \* \* \* \*

■ X. Section 512.525 is amended by revising paragraph (d)(4)(i) to read as follows:

#### § 512.525 Episodes.

(d) \* \* \*

(4) \* \* \*

(i) IPPS discharge under—

(A) MS-DRG 402, 426, 427, 428, 429, 430, 447, 448, 450, 451, 471, 472, 473; and

(B) On or after October 1, 2026 MS-DRG 523, 524, 525; or

\* \* \* \* \*

■ 39. Section 512.537 is amended by adding paragraph (b)(4) to read as follows:

#### § 512.537 Determination of the episode.

(b) \* \* \*

(4) The beneficiary is in a CJR-X episode and has a procedure performed at a TEAM participant during the 90-day post-discharge period after a CJR-X anchor hospitalization or CJR-X anchor procedure.

\* \* \* \* \*

■ 40. Section 512.540 is amended by—

■ a. In paragraph (a)(1)(i) by removing the phrase “the 24 MS-DRGs” and adding in its place the phrase “the MS-DRGs”; and

■ b. Revising paragraphs (b)(6) through (8).

The revisions read as follows:

#### § 512.540 Determination of preliminary target prices.

(b) \* \* \*

(6) *Prospective normalization factor.* Based on the episodes in the most recent calendar year of the baseline period for performance year 1 and for the entire baseline period starting in performance year 2, CMS calculates a prospective normalization factor at the MS-DRG/HCPCS region level, which is a multiplier that ensures that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, by doing the following:

(i) CMS applies risk adjustment multipliers, as specified in § 512.545(a)(1) through (3), to the most recent baseline year episodes for performance year 1 and to the entire baseline period episodes starting in performance year 2, to calculate the estimated risk-adjusted target price for all performance year episodes.

(ii) CMS divides the mean of the benchmark price for each episode across all hospitals and regions by the mean of the estimated risk-adjusted benchmark price calculated in § 512.540(b)(6)(i) for the same episode types across all hospitals and regions.

(7) Prospective and updated trend factors.

(i) *Prospective trend factor.* The prospective trend factor for each MS-DRG/HCPCS episode type and region is the average (arithmetic mean) of the multiplier, as calculated in paragraph (b)(7)(i) of this section, for that MS-DRG/HCPCS episode type and region and the national average for that MS-DRG/HCPCS episode type.

(A) CMS calculates a multiplier for each MS-DRG/HCPCS episode type and region which is applied to the most recent calendar year of the applicable baseline period.

(B) The multiplier is calculated using linear regression on the logarithmically

transformed average regional spending for each MS-DRG/HCPSC episode type in the baseline years and trend years at both the regional and national level.

(C) CMS exponentiates the coefficient from this regression to calculate the estimated annual change (where an exponentiated coefficient of 1 signifies no change) in average regional spending for each MS-DRG/HCPSC episode type from year to year.

(D) CMS squares the value in paragraph (C) to calculate the 2-year prospective trend factor.

(ii) *Updated prospective trend factor.* CMS calculates the updated prospective trend factor as the product of all the following factors:

(A) The prospective trend factor specified in paragraph (b)(7)(i) of this section.

(B) The APC update factor as specified in this paragraph (B). CMS calculates an APC update factor, after the corresponding calendar year inputs are published in the CY OPPS/ASC final rule, as the ratio of benchmark prices calculated with APC weights corresponding to the calendar year of the performance year to benchmark prices calculated with APC weights corresponding to the calendar year prior to the performance year.

(C) The MS-DRG update factor as specified in this paragraph (C). CMS calculates an MS-DRG update factor, after the corresponding fiscal year inputs are published in the FY IPPS/LTCH PPS final rule, for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year as the ratio of benchmark prices calculated with the second fiscal year inputs to benchmark prices calculated with the first fiscal year inputs.

(8) *Communication of preliminary target prices.* CMS communicates the preliminary target prices for each MS-DRG/HCPSC episode type for each region, and the preliminary target prices for each MS-DRG/HCPSC episode type specific to the TEAM participant before the performance year in which they apply. CMS communicates the APC and MS-DRG update factors after the corresponding calendar year and second fiscal year inputs are published with the corresponding calendar year and fiscal year final payment rules.

\* \* \* \* \*

■ 41. Section 512.545 is amended by—

■ a. Revising paragraphs (d)(1)

and (e)(1)(ii);

■ b. Adding paragraph (e)(1)(iii);

■ c. Redesignating paragraph (e) as paragraph (e)(2)(i);

■ d. Adding paragraph (e)(2)(ii); and

■ e. Revising paragraph (f).

The revisions and additions read as follows:

**§ 512.545 Determination of reconciliation target prices.**

\* \* \* \* \*

(d)(1) At the time of reconciliation, the preliminary target prices computed under § 512.540 are risk adjusted by applying the applicable beneficiary level and hospital-level risk adjustment factors specific to the beneficiary in the episode, as set forth in paragraphs (a)(1) through (6) of this section.

(2) CMS applies the coefficients estimated with the assigned first fiscal year MS-DRG/HCPSC inputs, as determined in § 512.550(c)(1), for episodes with anchor hospitalizations or anchor procedure end date in the fourth quarter of a performance year.

(e) \* \* \*

(1) \* \* \*

(ii) Episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year are calculated specific to the assigned first and second fiscal year MS-DRG/HCPSC episode type and region combination, as determined in § 512.550(c)(1). The benchmark prices and risk adjustment coefficients are calculated with the assigned first fiscal year MS-DRG/HCPSC inputs and applied to the realized case mix of the second fiscal year MS-DRG/HCPSC.

(iii) As applied, cannot exceed  $\pm 5$  percent of the prospective normalization factor (as specified in § 512.540(b)(6)).

(2) \* \* \*

(ii) For episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year, the final normalization factor is applied to each assigned first and second fiscal year MS-DRG/HCPSC episode type and region combination.

(f) CMS calculates a multiplier, referred to as the capped retrospective trend factor, for each MS-DRG/HCPSC episode type and region, which is applied during reconciliation to the most recent calendar year of the applicable baseline period.

(1)(i) The retrospective trend factor is calculated as the average regional capped performance year episode spending for each MS-DRG/HCPSC episode type divided by the average regional capped baseline period episode spending for each MS-DRG/HCPSC episode type.

(ii) For episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year, CMS calculates the retrospective trend factor as the average

regional capped performance year episode spending specific to the second fiscal year MS-DRG/HCPSC episode type divided by the average regional capped baseline period episode spending calculated with the assigned first fiscal year MS-DRG/HCPSC inputs.

(2) The retrospective trend factor is capped so that the maximum difference cannot exceed  $\pm 3$  percent of the updated prospective trend factor (as specified in § 512.540(b)(7)).

(3)(i) CMS applies the capped retrospective trend factor to the previously calculated normalized, risk adjusted target prices specific to each region and MS-DRG/HCPSC episode type, as specified in paragraph (e)(2) of this section, to calculate the reconciliation target prices, which are compared to performance year spending at reconciliation, as specified in § 512.550(c).

(ii) For episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year, the capped retrospective trend factor is applied specific to each assigned first and second fiscal year MS-DRG/HCPSC episode type and region combination.

■ 42. Section 512.547 is amended by—

■ a. In paragraph (a)(1)(i), removing the phrase “CY 2025” and adding in its place the phrase “July 1, 2024 through June 30, 2025”;

■ b. In paragraph (a)(1)(ii), removing the phrase “CY 2025” and adding in its place the phrase “July 1, 2023 through June 30, 2025”;

■ c. In paragraph (a)(1)(iii), removing the phrase “CY 2025” and adding in its place the phrase “July 1, 2024 through June 30, 2025”;

■ d. In paragraph (a)(2)(i), removing the phrase “CY 2025” and adding in its place the phrase “July 1, 2025 through June 30, 2026”;

■ e. In paragraph (a)(2)(iv), removing the phrase “CY 2026” and adding in its place the phrase “July 1, 2023 through June 30, 2025”;

■ f. In paragraph (a)(2)(v), removing the phrase “CY 2025” and adding in its place the phrase “July 1, 2024 through June 30, 2025”;

■ g. In paragraph (a)(3) introductory text, removing the phrase “years 3 through 5:” and adding in its place the phrase “year 3:”;

■ h. In paragraph (a)(3)(i), removing the phrase “CY 2025” and adding in its place the phrase “July 1, 2025 through June 30, 2026”;

■ i. In paragraph (a)(3)(ii), removing the phrase “2026” and adding in its place the phrase “2027”;

■ j. In paragraph (a)(3)(iii), removing the phrase “2026” and adding in its place the phrase “2027”;

■ k. In paragraph (a)(3)(iv), removing the phrase “CY 2026” and adding in its place the phrase “July 1, 2024 through June 30, 2026”;

■ l. In paragraph (a)(3)(v), removing the phrase “CY 2025” and adding in its place the phrase “July 1, 2025 through June 30, 2026”;

■ m. Adding paragraphs (a)(4) and (5). The additions read as follows:

**§ 512.547 Quality measures, composite quality score, and display of quality measures.**

(a) \* \* \*

(4) For performance year 4:

(i) For all episode categories: Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) with a July 1, 2026 through June 30, 2027 CQS baseline period.

(ii) For all episode categories: Hospital Harm—Falls with Injury (CMIT ID #1518) with a CY 2028 CQS baseline period.

(iii) For all episode categories: Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788) with a CY 2028 CQS baseline period.

(iv) For all episode categories: Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134) with a July 1, 2025 through June 30, 2027 CQS baseline period.

(v) For LEJR episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618) with a July 1, 2026 through July 30, 2027 CQS baseline period.

(vi) For LEJR and Spinal Fusion episodes: Information Transfer PRO-PM (CMIT ID #1797) with a CY 2028 CQS baseline period.

(5) For performance year 5:

(i) For all episode categories: Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) with a July 1, 2027 through June 30, 2028 CQS baseline period.

(ii) For all episode categories: Hospital Harm—Falls with Injury (CMIT ID #1518) with a CY 2029 CQS baseline period.

(iii) For all episode categories: Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788) with a CY 2029 CQS baseline period.

(iv) For all episode categories: Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134)

with a July 1, 2026 through June 30, 2028 CQS baseline period.

(v) For LEJR episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618) with a July 1, 2027 through July 30, 2028 CQS baseline period.

(vi) For LEJR and Spinal Fusion episodes: Information Transfer PRO-PM (CMIT ID #1797) with a CY 2029 CQS baseline period.

■ 43. Section 512.550 is amended by revising paragraph (c) to read as follows:

**§ 512.550 Reconciliation process and determination of the reconciliation payment or repayment amount.**

\* \* \* \* \*

(c) \* \* \*

(1) CMS assigns a first fiscal year MS-DRG by identifying diagnosis or procedure codes that change between the first and second fiscal year of the performance year per the fiscal year final payment rule MS-DRG definitions, for each episode with an anchor hospitalization or anchor procedure end date in the fourth quarter of a performance year. The first fiscal year MS-DRG will match the second fiscal year MS-DRG if there are no mapping changes for an initiating MS-DRG.

(i) CMS does not assign mapping changes for episodes with anchor hospitalization or anchor procedure end dates in the first three quarters of a performance year.

(2) CMS cancels an episode with an anchor hospitalization or anchor procedure end date in the fourth quarter of a performance year, in accordance with § 512.537(b), if the assigned first fiscal year MS-DRG is not specified in § 512.525(d).

(3) CMS determines the performance year spending for each episode included in the performance year (other than episodes that have been canceled in accordance with § 512.537(b)) for each MS-DRG/HCPSC episode type using claims data that is available 6 months after the end of the performance year.

(4) CMS calculates and applies the high-cost outlier cap for performance year episode spending by applying the calculation described in § 512.540(b)(4) to performance year episode spending for each MS-DRG/HCPSC episode type.

(5)(i) CMS applies the adjustments specified in § 512.545 to the preliminary target prices computed in accordance with § 512.540 to calculate the reconciliation target prices for each MS-DRG/HCPSC episode type.

(ii) CMS calculates the reconciliation target prices for each assigned first and second fiscal year MS-DRG/HCPSC

episode type for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year.

(6)(i) CMS aggregates the reconciliation target prices computed in accordance with paragraph (c)(3) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 512.537(b)) for each MS-DRG/HCPSC episode type.

(ii) CMS aggregates the reconciliation target prices for each assigned first and second fiscal year MS-DRG/HCPSC episode type for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year.

(7)(i) CMS subtracts the performance year spending amount determined under paragraphs (c)(1) and (2) of this section from the reconciliation target price amount determined under paragraph (c)(4) of this section for each MS-DRG/HCPSC episode type.

(i) CMS first subtracts the performance year spending amount from the reconciliation target amount for each assigned first and second fiscal year MS-DRG/HCPSC episode type, then sums values for each MS-DRG/HCPSC episode type for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year.

(8) CMS sums the values calculated under paragraph (c)(5) of this section across all MS-DRG/HCPSC episode types to determine the reconciliation amount.

(9)(i) CMS caps the performance year spending amount for each MS-DRG/HCPSC episode type determined under paragraphs (c)(3) and (4) of this section to equal the reconciliation target price computed in accordance with paragraph (c)(5) of this section for episode categories where the TEAM participant did not meet the low volume threshold of at least 31 episodes during the 3-year baseline period.

(ii) Low volume hospital episodes, including episode categories where CMS caps performance year spending, are included in the CQS, as calculated in § 512.547(b), and stop-loss/stop-gain thresholds, as applied at paragraph (e) of this section.

■ 44. Part 512 is amended by adding subpart F to read as follows:

**Subpart F—Comprehensive Care For Joint Replacement Expansion (CJR-X) Model**

Sec

**General**

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512.605 Definitions.

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512.615 APM options.

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512.622 Beneficiary notification.

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512.635 Quality measures, composite quality score, and display of quality measures.

#### Pricing Methodology

512.640 Determination of preliminary target prices.

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512.665 Data sharing with CJR–X participants.

#### Financial Arrangements and Beneficiary Incentives

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#### Medicare Program Waivers

512.695 CJR–X Medicare Program Waivers

### Subpart F—Comprehensive Care For Joint Replacement Expansion (CJR–X) Model

#### General

##### § 512.600 Basis and scope of subpart.

(a) *Basis*. This subpart implements the expansion of the Comprehensive Care for Joint Replacement (CJR) Model under section 1115A(c) of the Act. Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, and program integrity.

(b) *Scope*. This subpart sets forth the following:

(i) Participation in CJR–X.

(ii) Scope of episodes.  
(iii) Pricing methodology.  
(iv) Quality measures and quality reporting requirements.

(v) Reconciliation and review processes.

(vi) Data Sharing and other requirements.

(vii) Financial arrangements and beneficiary incentives.

(viii) Medicare program waivers.

(c) *Applicability*. Except as otherwise specified in this subpart, CJR–X participants are subject to the standard provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

##### § 512.605 Definitions.

For the purposes of this subpart, the following definitions are applicable unless otherwise stated:

*AAPM* stands for Advanced Alternative Payment Model.

*AAPM option* means the advanced alternative payment model option of CJR–X for CJR–X participants that provide their CMS EHR Certification ID and attest to their use of CEHRT in accordance with § 512.615.

*ACO* means an accountable care organization, as defined at § 425.20 of this chapter.

*ACO participant* has the meaning set forth in § 425.20 of this chapter.

*ACO provider/supplier* has the meaning set forth in § 425.20 of this chapter.

*Acute care hospital* means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

*Age bracket risk adjustment factor* means the coefficient of risk associated with a patient's age bracket, calculated as described in § 512.645(a)(1).

*Aggregated reconciliation target price* refers to the sum of the reconciliation target prices for all episodes attributed to a given CJR–X participant for a given performance year.

*Alignment payment* means a payment from a CJR–X collaborator to a CJR–X participant under a sharing arrangement, for the sole purpose of sharing the CJR–X participant's responsibility for making repayments to Medicare.

*Anchor hospitalization* means the initial hospital stay upon admission for a lower extremity joint replacement included in CJR–X, as described in § 512.625(a), for which the institutional claim is billed through the inpatient prospective payment system (IPPS). Anchor hospitalization also includes an inpatient hospital admission within 3 days after an outpatient Total Knee

Arthroplasty (TKA) or Total Hip Arthroplasty (THA).

*Anchor procedure* means a TKA or THA procedure related to an episode, as described in § 512.625(a), included in CJR–X that is permitted and paid for by Medicare when performed in a hospital outpatient department (HOPD) and billed through the Hospital Outpatient Prospective Payment System (OPPS), except when the beneficiary is admitted to an inpatient hospital stay within 3 days after the TKA or THA.

*APM* stands for Alternative Payment Model.

*Baseline episode spending* refers to total episode spending by all providers and suppliers associated with a given MS–DRG/HCPSC episode type for all hospitals in a given region during the baseline period.

*Baseline period* means the 3-year historical period used to construct the preliminary target price and reconciliation target price for a given performance year.

*Baseline year* means any one of the three years included in the baseline period.

*Benchmark price* means average standardized episode spending by all providers and suppliers associated with a given MS–DRG/HCPSC episode type for all hospitals in a given region during the applicable baseline period.

*Beneficiary economic risk adjustment factor* means the coefficient of risk associated with a patient's economic status, calculated as described in § 512.645(a)(3).

*CCN* stands for CMS certification number.

*CDI* stands for Community Deprivation Index.

*CEHRT* means certified electronic health record technology that meets the requirements set forth in § 414.1305 of this chapter.

*CJR* stands for the Comprehensive Care for Joint Replacement Model, which was an episode-based payment model tested by the Innovation Center from April 2016 to December 2024.

*CJR–X* stands for the Comprehensive Care for Joint Replacement Expanded Model.

*CJR–X activities* mean any activity related to promoting accountability for the quality, cost, and overall care for CJR–X beneficiaries and performance in the model, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty under the model.

*CJR-X beneficiary* means a beneficiary who meets the beneficiary inclusion criteria in § 512.620.

*CJR-X collaborator* means an ACO or one of the following Medicare-enrolled individuals or entities that enters into a sharing arrangement:

- (1) Skilled Nursing Facility (SNF).
- (2) Home Health Agency (HHA).
- (3) Long-Term Care Hospital (LTCH).
- (4) Inpatient Rehabilitation Facility (IRF).
- (5) Physician.
- (6) Nonphysician practitioner.
- (7) Therapist in private practice.
- (8) Comprehensive Outpatient Rehabilitation Facility (CORF).
- (9) Provider of outpatient therapy services.
- (10) Physician Group Practice (PGP).
- (11) Hospital.
- (12) Critical Access Hospital (CAH).
- (13) Non-Physician Provider Group Practice (NPPGP).
- (14) Therapy Group Practice (TGP).

*CJR-X data sharing agreement* means an agreement between the CJR-X participant and CMS that includes the terms and conditions for any beneficiary-identifiable data shared with the CJR-X participant under § 512.665.

*CJR-X HCC count risk adjustment factor* refers to the CJR-X Hierarchical Condition Category count, which is a categorical risk adjustment variable designed to reflect a beneficiary's overall health status during a 180-day lookback period by grouping similar diagnoses into one related category and counting the total number of diagnostic categories that apply to the beneficiary.

*CJR-X participant* means an acute care hospital with a CCN primary address located in the 50 United States, District of Columbia, or U.S. Territory that initiates LEJR episodes and is paid under both the IPPS and OPPI, unless it meets an exception in § 512.610(b).

*CJR-X payment* means a payment made by CMS only to CJR-X participants, or a payment adjustment made only to payments made to CJR-X participants, under the terms of CJR-X that is not applicable to any other providers or suppliers.

*CJR-X reconciliation report* means the report prepared after each reconciliation that CMS provides to the CJR-X participant notifying the CJR-X participant of the outcome of the reconciliation.

*Clinician engagement list* means the list of eligible clinicians or MIPS eligible clinicians that participate in CJR-X activities and have a contractual relationship with the CJR-X participant, and who are not listed on the financial arrangements list, as described in § 512.615(c).

*CMS Electronic Health Record (EHR) Certification ID* means the identification number that represents the combination of Certified Health Information Technology that is owned and used by providers and hospitals to provide care to their patients and is generated by the Certified Health Information Technology Product List.

*Collaboration agent* means an individual or entity that is not a CJR-X collaborator and that is either of the following:

- (1) A member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a CJR-X collaborator.

- (2) An ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating, and where the ACO is a CJR-X collaborator.

*Composite quality score (CQS)* means a score computed for each CJR-X participant to summarize the CJR-X participant's level of quality performance on specified quality measures as described in § 512.635.

*CORF* stands for comprehensive outpatient rehabilitation facility.

*Critical access hospital (CAH)* means a hospital designated under subpart F of part 485 of this chapter.

*Discount factor* means a set percentage included in the preliminary target price and adjusted for quality at reconciliation as described at § 512.645(g), which is intended to reflect Medicare's potential savings from CJR-X.

*Distribution arrangement* means a financial arrangement between a CJR-X collaborator that is an ACO, PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the ACO, PGP, NPPGP, or TGP.

*Distribution payment* means a payment from a CJR-X collaborator that is an ACO, PGP, NPPGP, or TGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

*DME* stands for durable medical equipment.

*Downstream collaboration agent* means an individual who is not a CJR-X collaborator or a collaboration agent and who is a member of a PGP, NPPGP, or TGP that has entered into a downstream distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or

employee, and where the PGP, NPPGP, or TGP is a collaboration agent.

*Downstream distribution arrangement* means a financial arrangement between a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP, NPPGP, or TGP.

*Downstream participant* means an individual or entity that has entered into a written arrangement with a CJR-X participant, CJR-X collaborator, collaboration agent, or downstream collaboration agent under which the downstream participant engages in one or more CJR-X activities.

*Dually eligible beneficiary* means a beneficiary enrolled in both Medicare and full Medicaid benefits.

*EHR* stands for electronic health record.

*Eligible clinician* means a clinician as defined in § 414.1305 of this chapter.

*Episode* means all Medicare Part A and B items and services described in § 512.625(b) (and excluding the items and services described in § 512.625(c)) that are furnished to a beneficiary described in § 512.620 during the time period that begins on the date of the beneficiary's admission to an anchor hospitalization or the date of the anchor procedure, as described at § 512.630(c), and ends on the 90th day following the date of discharge from the anchor hospitalization or anchor procedure, with the date of discharge or date of the anchor procedure itself being counted as the first day in the 90-day post-discharge period, as described at § 512.630(d). In the case that an anchor hospitalization for the same episode type occurs within 3 days of an anchor procedure, the anchor procedure episode is canceled, and the episode start date for the anchor hospitalization is the same as the outpatient procedure.

*Episode type* refers to the subset of episodes that are associated with a given MS-DRG/HCCPCS, as set forth at § 512.640(a)(1).

*Final normalization factor* refers to the mean of the benchmark price for each MS-DRG/HCCPCS episode type and region divided by the mean of the risk-adjusted benchmark price for the same MS-DRG/HCCPCS episode type and region.

*Financial arrangements list* means the list of eligible clinicians or MIPS eligible clinicians that have a financial arrangement with the CJR-X participant, CJR-X collaborator, collaboration agent, and downstream collaboration agent, as described in § 512.615(b).

*Gainsharing payment* means a payment from a CJR-X participant to a

CJR–X collaborator, under a sharing arrangement, composed of only reconciliation payments, internal cost savings, or both.

*HCPCS* stands for Healthcare Common Procedure Coding System, which is used to bill for items and services.

*HHA* means a Medicare-enrolled home health agency.

*High-cost outlier cap* refers to the 99th percentile of regional spending for a given MS DRG/HCPCS episode type, region, and baseline year, which is the amount at which episode spending would be capped for purposes of determining baseline and performance year episode spending.

*Hospital* means a hospital as defined in section 1886(d)(1)(B) of the Act.

*Hospital discharge planning* means the standards set forth in § 482.43 of this chapter.

*ICD–CM* stands for International Classification of Diseases, Clinical Modification.

*Inpatient measure composite quality score* means the sum of inpatient quality measure point values capped at 20 points.

*Internal cost savings* means the measurable, actual, and verifiable cost savings realized by the CJR–X participant resulting from care redesign undertaken by the CJR–X participant in connection with providing items and services to CJR–X beneficiaries within an episode. Internal cost savings does not include savings realized by any individual or entity that is not the CJR–X participant.

*IPF* stands for inpatient psychiatric facility.

*IPPS* stands for Inpatient Prospective Payment System, which is the payment system for subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act.

*IRF* stands for inpatient rehabilitation facility.

*LIS* stands for Medicare Part D Low-Income Subsidy.

*Lower-extremity joint replacement* (LEJR) means any hip, knee, or ankle replacement that is paid under MS–DRG 469, 470, 521, or 522 through the IPPS or HCPCS code 27447 or 27130 through the OPPI.

*Low-volume hospital* refers to a hospital with fewer than 31 FFS LEJR episodes during the applicable baseline period.

*LTCH* stands for long-term care hospital as defined in section 1861(ccc) of the Act.

*Medicare severity diagnosis-related group* (MS–DRG) means, for the purposes of this model, the classification of inpatient hospital

discharges updated in accordance with § 412.10 of this chapter.

*Medicare-dependent, small rural hospital* (MDH) means a specific type of hospital that meets the classification criteria specified under § 412.108 of this chapter.

*Member of the NPPGP or NPPGP member* means a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP his or her right to receive Medicare payment.

*Member of the PGP or PGP member* means a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP his or her right to receive Medicare payment.

*Member of the TGP or TGP member* means a therapist who is an owner or employee of a TGP and who has reassigned to the TGP his or her right to receive Medicare payment.

*MIPS* stands for Merit-based Incentive Payment System

*MIPS eligible clinician* means a clinician as defined in § 414.1305 of this chapter.

*Model-specific payment* means a payment made by CMS only to CJR–X participants and includes, unless otherwise specified, the reconciliation payment.

*Model start date* means the start of the model performance period on October 1, 2027.

*Non-AAPM option* means the option of a CJR–X participant that does not attest to the use of CEHRT as described in § 512.615.

*Nonphysician practitioner* means one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b)).

(5) A clinical social worker (as defined at § 410.73(a)).

(6) A registered dietitian or nutrition professional (as defined at § 410.134).

*NPI* stands for National Provider Identifier.

*NPPGP* stands for non-physician provider group practice, which means an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.

*Net payment reconciliation amount* (NPRA) means the dollar amount

calculated in accordance with § 512.650(c).

*OIG* stands for the Department of Health and Human Services' Office of the Inspector General.

*OP* means an outpatient procedure for which the institutional claim is billed by the hospital through the OPPI.

*OPPI* stands for the Outpatient Prospective Payment System.

*Outpatient composite quality score* means the sum of outpatient quality measure points values, capped at 20 points

*Overall composite quality score* means the sum of the weighted average of the inpatient measure composite quality score and the outpatient measure composite quality score, capped at 20 points.

*PAC* stands for post-acute care.

*PAC provider* is a home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long-term care hospital (LTCH), as defined in section 1899B(a)(2) of the Act.

*Performance year* (PY) means a 12-month period beginning on October 1 and ending on September 30 of the following year to align with the Inpatient Prospective Payment System Fiscal Year.

*Performance year spending* means the sum of standardized Medicare claims payments during the performance year for the items and services that are included in the episode in accordance with § 512.625(b), excluding the items and services described in § 512.625(c).

*PGP* stands for physician group practice.

*Physician* has the meaning set forth in section 1861(r) of the Act.

*Preliminary target price* refers to the target price provided to the CJR–X participant prior to the start of the performance year, which is subject to adjustment at reconciliation, as set forth at § 512.640.

*Prospective normalization factor* refers to the multiplier incorporated into the preliminary target price to ensure that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, calculated as set forth in § 512.640(b)(6).

*Prospective trend factor* refers to the multiplier incorporated into the preliminary target price to estimate changes in spending patterns between the baseline period and the performance year, calculated as set forth in § 512.640(b)(7).

*Provider of outpatient therapy services* means an entity that is enrolled in Medicare as a provider of therapy

services and furnishes one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

*Reconciliation payment amount* means the amount that CMS may owe to a CJR-X participant after reconciliation as determined in accordance with § 512.650(g).

*Reconciliation target price* means the target price applied to an episode at reconciliation, as determined in accordance with § 512.645.

*Region* means one of the nine U.S. census divisions, as defined by the U.S. Census Bureau, with the U.S. territories included in Census Division 9.

*Reorganization event* refers to a merger, consolidation, spin off or other restructuring that results in a new hospital entity under a given CCN.

*Repayment amount* means the amount that the CJR-X participant may owe to Medicare after reconciliation as determined in accordance with § 512.650(g).

*Retrospective trend factor* refers to the multiplier incorporated into the reconciliation target price to estimate realized changes in spending patterns during the performance year, calculated as set forth in § 512.645(f).

*Rural hospital* means an IPPS hospital that meets one of the following criteria:

(1) Is located in a rural area as defined under § 412.64 of this chapter.

(2) Is located in a rural census tract defined under § 412.103(a)(1) of this chapter.

*Safety net hospital* means a hospital in the top 25th percentile in their region for percentage of FFS LEJR inpatient episodes provided to dually eligible beneficiaries during the applicable baseline period.

*Sharing arrangement* means a financial arrangement between a CJR-X participant and a CJR-X collaborator for the sole purpose of making gainsharing payments or alignment payments under CJR-X.

*SNF* stands for skilled nursing facility as defined in section 1819(a) of the Act.

*Sole community hospital (SCH)* means a hospital that meets the classification criteria specified in § 412.92 of this chapter.

*Swing-bed hospital* means a hospital that meets the definition specified in § 413.114 of this chapter.

*TAA* stands for total ankle arthroplasty.

*TGP or therapy group practice* means an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee who is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN.

*THA* means total hip arthroplasty.

*Therapist* means one of the following individuals as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

*Therapist in private practice* means a therapist that—

(1) Complies with the special provisions for physical therapists in private practice in § 410.60(c) of this chapter;

(2) Complies with the special provisions for occupational therapists in private practice in § 410.59(c) of this chapter; or

(3) Complies with the special provisions for speech-language pathologists in private practice in § 410.62(c) of this chapter.

*TIN* stands for taxpayer identification number.

*TKA* stands for total knee arthroplasty.

## CJR-X Participation

### § 512.610 Mandatory participation.

(a) *General*

(1) CJR-X participants, as defined in § 512.605, must participate in CJR-X, except as specified in paragraph (b) of this section.

(2) CJR-X participants will remain CJR-X participants, unless they no longer meet the definition of CJR-X participant, CMS terminates CJR-X, or the CJR-X participant receives notice of termination from CJR-X in accordance with § 512.165.

(b) *Exceptions.* CMS excludes from CJR-X hospitals that meet any of the following criteria:

(1) Is a TEAM participant as defined at § 512.505.

(2) Is located in the State of Maryland.

### § 512.615 APM options.

(a) *CJR-X APM options.* A CJR-X participant may choose either of the following options based on their CEHRT use:

(1) *AAPM option.* A CJR-X participant may select the AAPM option by attesting in a form and manner and by a date specified by CMS to their use of CEHRT, as defined in § 414.1305 of this chapter, on an annual basis prior to the start of each performance year.

(i) A CJR-X participant that selects the AAPM option as provided for in

paragraph (a)(1) must provide their CMS electronic health record certification ID in a form and manner and by a date specified by CMS on annual basis prior to the end of each performance year.

(ii) A CJR-X participant that selects the AAPM option as provided for in paragraph (a)(1) must retain documentation of their attestation to CEHRT use and provide access to the documentation in accordance with § 512.135.

(2) *Non-AAPM option.* CMS assigns the CJR-X participant to the non-AAPM option if the CJR-X participant does not attest in a form and manner and by a date specified by CMS to their use of CEHRT as defined in § 414.1305 of this chapter.

(b) *Financial arrangements list.* A CJR-X participant with CJR-X collaborators, collaboration agents, or downstream collaboration agents during a performance year must submit to CMS a financial arrangements list in a form and manner and by a date specified by CMS on a quarterly basis for each performance year. The financial arrangements list must include the following:

(1) *CJR-X collaborators.* For each physician, nonphysician practitioner, or therapist who is a CJR-X collaborator during the performance year:

(i) The name, TIN, and NPI of the CJR-X collaborator.

(ii) The start date and, if applicable, end date of the sharing arrangement between the CJR-X participant and the CJR-X collaborator.

(2) *Collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a collaboration agent during the performance year:

(i) The name, TIN, and NPI of the collaboration agent and the name and TIN of the CJR-X collaborator with which the collaboration agent has entered into a distribution arrangement.

(ii) The start date and, if applicable, end date of the distribution arrangement between the CJR-X collaborator and the collaboration agent.

(3) *Downstream collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a downstream collaboration agent during the performance year:

(i) The name, TIN, and NPI of the downstream collaboration agent and the name and TIN of the collaboration agent with which the downstream collaboration agent has entered into a downstream distribution arrangement.

(ii) The start date and, if applicable, end date of the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.



(c) *Clinician engagement list.* A CJR-X participant must submit to CMS a clinician engagement list in a form and manner and by a date specified by CMS on a quarterly basis during each performance year. The clinician engagement list must include the following:

(1) For each physician, nonphysician practitioner, or therapist who is not on a CJR-X participant's financial arrangements list during the performance year but who does have a contractual relationship with the CJR-X participant and participates in CJR-X activities during the performance year:

(i) The name, TIN, and NPI of the physician, nonphysician practitioner, or therapist.

(ii) The start date and, if applicable, the end date of the contractual relationship between the physician, nonphysician practitioner, or therapist and the CJR-X participant.

(d) *Attestation to no individuals.* A CJR-X participant with no individuals that meet the criteria specified in paragraphs (b)(1) through (3) of this section for the financial arrangements list or paragraph (c) of this section for the clinician engagement list must attest in a form and manner and by a date specified by CMS that there are no financial arrangements or clinician engagements to report.

(e) *Documentation requirements.* A CJR-X participant that submits a financial arrangements list specified in paragraph (b) of this section or a clinician engagement list specified in paragraph (c) of this section must retain and provide access to the documentation in accordance with § 512.135.

### Beneficiary Population

#### § 512.620 Beneficiary inclusion criteria.

(a) An individual is a CJR-X beneficiary if, upon admission for an anchor procedure or anchor hospitalization, the individual:

(1) Is enrolled in Medicare Parts A and B;

(2) Has Medicare as their primary payer;

(3) Is not eligible for Medicare on the basis of having end stage renal disease, as described at § 406.13 of this chapter;

(4) Is not enrolled in any managed care plan (for example, Medicare Advantage, health care prepayment plans, or cost-based health maintenance organizations);

(5) Is not covered under a United Mine Workers of America health care plan; and

(6) Is in an episode.

(b) The episode is canceled in accordance with § 512.630(e) if at any

time during the episode a beneficiary no longer meets all of the criteria in paragraph (a) of this section.

#### § 512.622 Beneficiary notification.

(a) *CJR-X participant beneficiary notification.*

(1) *Notification to beneficiaries.* Each CJR-X participant must provide written notification to each CJR-X beneficiary of his or her inclusion in the CJR-X model.

(2) *Timing of notification.* Prior to discharge from either the anchor hospitalization or the anchor procedure, as applicable, the CJR-X participant must provide the CJR-X beneficiary with a beneficiary notification as described in paragraph (a)(4) of this section.

(3) *List of CJR-X beneficiaries who have received a notification.* The CJR-X participant must be able to generate a list of all CJR-X beneficiaries who have received such notification, including the date on which the notification was provided to the CJR-X beneficiary, and provide such list to CMS or its designee upon request.

(4) *Content of notification.* The beneficiary notification must contain all of the following:

(i) A detailed explanation of CJR-X and how it might be expected to affect the CJR-X beneficiary's care.

(ii) That the CJR-X beneficiary retains freedom of choice to choose providers, suppliers, and services.

(iii) Explanation of how the CJR-X beneficiary can access care records and claims data through an available patient portal, if applicable, and how to share access to Blue Button<sup>®</sup> electronic health information with caregivers.

(iv) Explanation of the type of beneficiary-identifiable claims data the CJR-X participant may receive.

(v) A statement that all existing Medicare beneficiary protections continue to be available to the CJR-X beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations or the 1-800-MEDICARE helpline.

(vi) A list of the CJR-X collaborators with which the CJR-X participant has a sharing arrangement. This requirement may be fulfilled by the CJR-X participant including in the detailed notification a publicly available Web address where the CJR-X beneficiary may access the list.

(b) *CJR-X collaborator notice.* The CJR-X participant must require every CJR-X collaborator that furnishes an item or service to a CJR-X beneficiary during an episode to provide written notice, to be developed by CMS, to the CJR-X beneficiary that describes general information on the quality and payment

incentives under CJR-X, and the existence of the CJR-X collaborator's sharing arrangement.

(1) The notice must be provided no later than the time at which the CJR-X beneficiary first receives an item or service from the CJR-X collaborator during an episode. In circumstances where, due to the CJR-X beneficiary's condition, it is not feasible to provide notification at such time, the notification must be provided to the CJR-X beneficiary or his or her representative as soon as is reasonably practicable.

(2) The CJR-X collaborator must provide to CMS upon request, a list of all CJR-X beneficiaries who received such a notice, including the date on which the notice was provided to the CJR-X beneficiary.

(c) *Discharge planning notice.* The CJR-X participant must provide the CJR-X beneficiary with a written notice of any potential financial liability associated with non-covered services recommended or presented as an option as part of discharge planning, no later than the time that the CJR-X beneficiary discusses a particular post-acute care option or at the time the CJR-X beneficiary is discharged from an anchor procedure or anchor hospitalization, whichever occurs earlier.

(1) If the CJR-X participant knows or should have known that the CJR-X beneficiary is considering or has decided to receive a non-covered post-acute care service or other non-covered associated service or supply, the CJR-X participant must notify the CJR-X beneficiary in writing that the service would not be covered by Medicare.

(2) If the CJR-X participant is discharging a CJR-X beneficiary to a SNF after an inpatient hospital stay, and the CJR-X beneficiary is being transferred to or is considering a SNF that would not qualify under the SNF 3-day waiver in § 512.695(b), the CJR-X participant must notify the CJR-X beneficiary in accordance with paragraph (c)(1) of this section that the CJR-X beneficiary will be responsible for payment for the services furnished by the SNF during that stay, except those services that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

(d) *Access to records and retention.* The CJR-X participant must provide access to the notifications and lists described in paragraphs (a), (b), and (c) of this section to CMS, or its designees, in accordance with § 512.135.



## Episode of Care

### § 512.625 Scope of episode.

(a) *Lower extremity joint replacement (LEJR) procedures.* The MS-DRGs and HCPCS codes included in the episodes are as follows:

(1) IPPS discharge under MS-DRG 469, 470, 521, or 522.

(2) OPPS claim for HCPCS codes 27130 or 27447.

(b) *Included services.* All Medicare Part A and B items and services are included in the episode, except as specified in paragraph (c) of this section. These services include, but are not limited to, the following:

(1) Physicians' services.

(2) Inpatient hospital services (including hospital readmissions).

(3) IPF services.

(4) LTCH services.

(5) IRF services.

(6) SNF services.

(7) HHA services.

(8) Hospital outpatient services.

(9) Outpatient therapy services.

(10) Clinical laboratory services.

(11) DME.

(12) Part B drugs and biologic, except for those excluded under paragraph (c) of this section.

(13) Hospice services.

(14) Part B professional claims dated in the 3 days prior to an anchor hospitalization if a claim for the surgical procedure for the same episode type is not detected as part of the hospitalization because the procedure was performed by the CJR-X participant on an outpatient basis, but the patient was subsequently admitted as an inpatient.

(c) *Excluded services.* The following items, services, and payments are excluded from the episode:

(1) Select items and services considered unrelated to the anchor hospitalization or the anchor procedure for episodes in the baseline period and performance year, including, but not limited to, the following:

(i) Inpatient hospital admissions for MS-DRGs that group to the following categories of diagnoses:

(A) Oncology.

(B) Trauma medical.

(C) Organ transplant.

(D) Ventricular shunt.

(ii) Inpatient hospital admissions that fall into the following Major Diagnostic Categories (MDCs):

(A) MDC 02 (Diseases and Disorders of the Eye).

(B) MDC 14 (Pregnancy, Childbirth, and Puerperium).

(C) MDC 15 (Newborns).

(D) MDC 25 (Human Immunodeficiency Virus).

(2) New technology add-on payments, as defined in part 412, subpart F of this chapter for episodes in the baseline period and performance year.

(3) Transitional pass-through payments for medical devices as defined in § 419.66 of this chapter for episodes initiated in the baseline period and performance year.

(4) Hemophilia clotting factors provided in accordance with § 412.115 of this chapter for episodes in the baseline period and performance year.

(5) Part B payments for low-volume drugs, high-cost drugs and biologics, and blood clotting factors for hemophilia for episodes in the baseline period and performance year, billed on outpatient, carrier, and DME claims, defined as—

(i) Drug/biologic HCPCS codes that are billed in fewer than 31 episodes in total across all episodes in CJR-X during the baseline period;

(ii) Drug/biologic HCPCS codes that are billed in at least 31 episodes in the baseline period and have a mean allowed cost of greater than \$25,000 per episode in the baseline period; and

(iii) HCPCS codes corresponding to clotting factors for hemophilia patients, identified in the quarterly average sales price file for certain Medicare Part B drugs and biologics as HCPCS codes with clotting factor equal to 1, HCPCS codes for new hemophilia clotting factors not included in the baseline period, and other HCPCS codes identified as hemophilia.

(6) Part B payments for low-volume drugs, high-cost drugs and biologics, and blood clotting factors for hemophilia for episodes initiated in the performance year, billed on outpatient, carrier, and DME claims, defined as—

(i) Drug/biologic HCPCS codes that were not captured in the baseline period and appear in 10 or fewer episodes in the relevant performance year;

(ii) Drug/biologic HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the relevant performance year, and have a mean cost of greater than \$25,000 per episode in the relevant performance year; and

(iii) Drug/biologic HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the relevant performance year, have a mean cost of \$25,000 or less per episode in the relevant performance year, and correspond to a drug/biologic that appears in the baseline period but was assigned a new HCPCS code between the baseline period and the relevant performance year.

(iv) HCPCS codes for new hemophilia clotting factors not included in the baseline period.

(d) *CJR-X exclusions list.* The list of excluded MS-DRGs, MDCs, and HCPCS codes is posted on the CMS website.

(e) *Updating the CJR-X exclusions list.* The list of excluded services is updated through rulemaking to reflect any of the following:

(1) Changes to the MS-DRGs under the IPPS.

(2) Coding changes.

(3) Other issues brought to CMS' attention.

### § 512.630 Determination of the episode.

(a) *Timing of episodes.* Episodes initiated on or after October 1, 2027.

(b) *Episode attribution.* All items and services included in the episode are attributed to the CJR-X participant at which the anchor hospitalization or anchor procedure, as applicable, occurs.

(c) *Episode initiation.* An episode is initiated by—

(1) A beneficiary's admission to a CJR-X participant for an anchor hospitalization that is paid under a MS-DRG specified in § 512.625(a); or

(2) A beneficiary's receipt of an anchor procedure billed under a HCPCS code specified in § 512.625(a). If an anchor hospitalization is initiated on the same day as or within 3 days of an outpatient procedure for the same episode type, the episode start date will be that of the outpatient procedure rather than the admission date, and an anchor procedure will not be initiated.

(d) *Episode conclusion.*

(1) An episode ends on the 90th day following the date of the anchor procedure or the date of discharge from the anchor hospitalization, as applicable, with the date of the anchor procedure or the date of discharge from the anchor hospitalization being counted as the first day in the 90-day post-discharge period.

(e) *Cancellation of an episode.* The episode is canceled and is not included in the reconciliation calculation as specified in § 512.650 if any of the following occur:

(1) The beneficiary ceases to meet any criterion listed in § 512.620.

(2) The beneficiary dies at any point during the episode.

(3) The episode qualifies for cancellation due to extreme and uncontrollable circumstances. An extreme and uncontrollable circumstance occurs if both of the following criteria are met:

(i) The CJR-X participant has a CCN primary address that—

(A) Is located in an emergency area, as those terms are defined in section

1135(g) of the Act, for which the Secretary has issued a waiver under section 1135; and

(B) Is located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

(ii) The date of admission to the anchor hospitalization or the date of the anchor procedure is during an emergency period (as defined in section 1135(g) of the Act) or in the 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins.

(4) The beneficiary is in a TEAM episode and receives a LEJR procedure at a CJR-X participant during the 30-day post-discharge period after a TEAM anchor hospitalization or TEAM anchor procedure.

### **Quality Measures and Composite Quality Score**

#### **§ 512.635 Quality measures, composite quality score, and display of quality measures.**

(a) *Quality measures.* CMS calculates the quality measures used to evaluate the CJR-X participant's performance using Medicare claims data or patient-reported outcomes data reported under existing CMS quality reporting programs, including but not limited to the Hospital Inpatient Quality Reporting Program and the Hospital Outpatient Quality Reporting Program. The following quality measures are used for public reporting and for determining the CJR-X participant's CQS as described in paragraph (b) of this section:

(1) For all inpatient episodes: Hospital-level Risk-Standardized Complication Rate following elective primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (CMIT ID #350).

(2) For all outpatient episodes: Hospital Visits within 7 days of Hospital Outpatient Department Surgery (CMIT ID #344, OP-36).

(3) For all inpatient episodes: Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS) (CMIT ID #338).

(4) For all outpatient episodes: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Survey (OAS CAHPS) (CMIT #162, OP-46).

(5) For all inpatient episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure ((PRO-PM) CMIT ID #1618).

(b) *Calculation of the composite quality score (CQS).* CMS calculates an overall composite quality score during reconciliation, capped at 20 points, for

each CJR-X participant for the relevant performance year. The overall composite quality score equals the sum of the inpatient measure composite quality score, as described in paragraph (b)(1) of this section, and the outpatient measure composite quality score, as described in paragraph (b)(2) of this section:

(1) CMS calculates the inpatient measure composite quality score by summing the following:

(i) The CJR-X participant's quality performance points for the measure identified in paragraph (a)(1) of this section. This measure is weighted at 50 percent of the inpatient composite quality score.

(ii) The CJR-X participant's quality performance points for the measure identified in paragraph (a)(3) of this section. This measure is weighted at 40 percent of the inpatient composite quality score.

(iii) The CJR-X participant's quality performance points for the measure identified in paragraph (a)(5) of this section. This measure is weighted at 10 percent of the inpatient composite quality score.

(2) CMS calculates the outpatient measure composite quality score by summing the following:

(i) The CJR-X participant's quality performance points for the measure identified in paragraphs (a)(2) of this section. This measure is weighted at 50 percent of the outpatient composite quality score.

(ii) The CJR-X participant's quality performance points for the measure identified in paragraphs (a)(4) of this section. This measure is weighted at 40 percent of the outpatient composite quality score.

(iii) The CJR-X participant's quality performance points for the measure identified in paragraph (a)(5) of this section. This measure is weighted at 10 percent of the inpatient composite quality score.

(c) *Quality performance points.* CMS calculates quality performance points for each quality measure based on the CJR-X participant's performance relative to the distribution of performance of all hospitals that are eligible for payment under IPPS and meet the minimum patient case or survey count for that measure.

(1) For the measures described in paragraphs (a)(1) and (a)(2) of this section, CMS assigns the CJR-X participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(i) 10.00 for ≥90th.

(ii) 9.25 for ≥80th and <90th.  
(iii) 8.50 for ≥70th and <80th.  
(iv) 7.75 for ≥60th and <70th.  
(v) 7.00 for ≥50th and <60th.  
(vi) 6.25 for ≥40th and <50th.  
(vii) 5.50 for ≥30th and <40th.  
(viii) 0.00 for <30th.

(2) For the measure described in paragraphs (a)(3) and (4) of this section, CMS assigns the CJR-X participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(i) 8.00 for ≥90th.  
(ii) 7.40 for ≥80th and <90th.  
(iii) 6.80 for ≥70th and <80th.  
(iv) 6.20 for ≥60th and <70th.  
(v) 5.60 for ≥50th and <60th.  
(vi) 5.00 for ≥40th and <50th.  
(vii) 5.40 for ≥30th and <40th.  
(viii) 0.00 for <30th.

(3) For the measure described in paragraph (a)(5) of this section, CMS assigns the CJR-X participant's measure value to a performance percentile and then CMS assigns quality performance points based on the following performance percentile scale:

(i) 2.00 for ≥90th.  
(ii) 1.85 for ≥80th and <90th.  
(iii) 1.70 for ≥70th and <80th.  
(iv) 1.55 for ≥60th and <70th.  
(v) 1.40 for ≥50th and <60th.  
(vi) 1.25 for ≥40th and <50th.  
(vii) 1.10 for ≥30th and <40th.  
(viii) 0.00 for <30th.

(d) *Exception for hospitals without a measure value.*

(1) If the CJR-X participant is without a measure value that would allow CMS to assign quality performance points for that quality measure, CMS assigns the 50th percentile quality performance points to the CJR-X participant for the individual measure.

(2) A CJR-X participant will not have a measure value for—

(i) The measure described in paragraph (a)(1) of this section, if the CJR-X participant does not meet the minimum 25 patient case count.

(ii) The measure described in paragraph (a)(2) of this section, if the CJR-X participant does not meet the minimum 25 patient case count.

(iii) The measure described in paragraph (a)(3) of this section, if the CJR-X participant does not meet the minimum 100 completed surveys.

(iv) The measure described in paragraph (a)(4) of this section, if the CJR-X participant does not meet the minimum 100 completed surveys.

(v) The measure described in paragraph (a)(5) of this section, if the CJR-X participant does not meet the minimum 25 patient case count.

(e) *Display of quality measures.*

(1) CMS displays quality measure results on the publicly available CMS website that is specific to CJR–X, in a form and manner consistent with other publicly reported measures.

(2) CMS shares quality measures with the CJR–X participant prior to display on the CMS website. Quality measure performance in performance year 1 will be reported in Calendar Year 2029. Subsequent years will be reported in the year following the performance period.

### Pricing Methodology

#### § 512.640 Determination of preliminary target prices.

(a) *Preliminary target price application.* CMS establishes preliminary target prices for CJR–X participants for each performance year of the model as follows:

(1) *MS–DRG/HCPSC episode type.* CMS uses the MS–DRGs and, as applicable, HCPSC codes specified in § 512.625(d) when calculating the preliminary target prices for each MS–DRG/HCPSC episode type.

(i) CMS determines a separate preliminary target price for each of the MS–DRGs specified in § 512.625(a)(1).

(ii) Preliminary target prices for MS–DRG 470 include HCPSC 27130 and 27447.

(2) *Applicable time period for preliminary target prices.* CMS calculates preliminary target prices for each MS–DRG/HCPSC episode type and region for each performance year and applies the preliminary target price to each episode based on the episode's date of discharge from the anchor hospitalization or the episode's date of the anchor procedure, as applicable.

(3) *Episodes that begin in one performance year and end in the subsequent performance year.* CMS applies the preliminary target price to the episode based on the date of discharge from the anchor hospitalization or the date of the anchor procedure, as applicable, and reconciles the episode based on the date of discharge from the anchor hospitalization or the date of the anchor procedure.

(4) *Exception for low-volume hospitals.* CJR–X participants with fewer than 31 episodes in the applicable baseline period do not receive preliminary target prices for the upcoming performance year and are not eligible for reconciliation for that performance year.

(b) *Preliminary target price calculation.*

(1) CMS calculates preliminary target prices based on average baseline episode spending for the region where

the CJR–X participant is located. The region used for calculating the preliminary target price corresponds to the U.S. Census Division associated with the primary address of the CCN of the CJR–X participant, and the regional episode spending amount is based on all hospitals in the region, except for those excluded from CJR–X as specified in § 512.610(b).

(2) CMS uses the following baseline periods to determine baseline episode spending:

(i) Performance Year 1: Episodes with anchor hospitalization start dates or anchor procedure dates beginning on or after October 1, 2023 and anchor hospitalization discharge dates or anchor procedure dates between October 1, 2023 and September 30, 2026.

(ii) Performance Year 2 and future performance years: CMS uses the same cadence described in paragraph (i) of this section to roll the baseline period forward a year to construct the baseline period.

(3) CMS calculates the benchmark price as the weighted average of baseline episode spending, applying the following weights:

(i) Baseline episode spending from baseline year 1 is weighted at 17 percent.

(ii) Baseline episode spending from baseline year 2 is weighted at 33 percent.

(iii) Baseline episode spending from baseline year 3 is weighted at 50 percent.

(4) *Exception for high episode spending.* CMS applies a high-cost outlier cap to baseline episode spending at the 99th percentile of regional spending for each of the MS–DRG/HCPSC episode types specified in § 512.640(a)(1) for each baseline year individually.

(5) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* Certain Medicare incentive programs and add-on payments are excluded from baseline episode spending by using, with certain modifications, the CMS Price (Payment) Standardization Detailed Methodology.

(6) *Prospective normalization factor.* Based on the episodes in the baseline period, CMS calculates a prospective normalization factor, at the MS–DRG/HCPSC region level, so that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, by:

(i) Applying risk adjustment multipliers, as specified in § 512.645(a)(1) through (3), to baseline period episodes to calculate the

estimated risk-adjusted target price for all performance year episodes; and

(ii) Dividing the mean of the benchmark price for each episode across all hospitals and regions by the mean of the estimated risk-adjusted benchmark price calculated in § 512.640(b)(6)(i) for the same episode types across all hospitals and regions.

(7) *Prospective trend factor.* The prospective trend factor for each MS–DRG/HCPSC episode type and region is the average (arithmetic mean) of the multiplier, as calculated in paragraph (i) of this section, for that MS–DRG/HCPSC episode type and region and the national average for that MS–DRG/HCPSC episode type.

(i) CMS calculates a multiplier for each MS–DRG/HCPSC episode type and region and applies that multiplier to the most recent calendar year of the applicable baseline period. The multiplier is calculated using linear regression on the logarithmically transformed average regional spending for each MS–DRG/HCPSC episode type in the baseline years at both the regional and national level.

(ii) CMS exponentiates the coefficient from this regression to calculate the estimated annual change (where an exponentiated coefficient of 1 signifies no change) in average regional spending for each MS–DRG/HCPSC episode type from year to year.

(8) *Discount factor.* CMS incorporates a discount factor of 2 percent to the CJR–X participant's preliminary episode target prices intended to reflect Medicare's potential savings from CJR–X.

(9) *Communication of preliminary target prices.* CMS communicates, in a form and manner specified by CMS, the preliminary target prices for each MS–DRG/HCPSC episode type for each region to the CJR–X participant before the performance year in which they apply.

#### § 512.645 Determination of reconciliation target prices.

CMS calculates the reconciliation target price as follows:

(a) *Risk adjustment factors.* CMS risk adjusts the preliminary episode target prices calculated under § 512.640 at the beneficiary level using a CJR–X Hierarchical Condition Category (HCC) count risk adjustment factor, an age bracket risk adjustment factor, a beneficiary economic risk adjustment factor, and the additional factors specified in paragraph (a)(6) of this section, and at the hospital level using a hospital bed size risk adjustment factor and a safety net hospital risk adjustment factor.

(1) The CJR-X HCC count risk adjustment factor uses five variables, representing beneficiaries with zero, one, two, three, or four or more CMS-HCC conditions based on a 180-day lookback period that begins 181 days prior to the anchor hospitalization or anchor procedure and ends on the day prior to the anchor hospitalization or anchor procedure.

(2) The age bracket risk adjustment factor uses four variables, representing beneficiaries in the following age groups as of the first day of the episode:

- (i) Less than 65 years.
- (ii) 65 to less than 75 years.
- (iii) 75 years to less than 85 years.
- (iv) 85 years or more.

(3) The beneficiary economic risk adjustment factor uses two variables, representing beneficiaries that, as of the first day of the episode:

(i) Meet one or more of the following economic measures:

(A) National CDI above the 80th percentile.

(B) Eligibility for the low-income subsidy.

(C) Eligibility for full Medicaid benefits.

(ii) Do not meet any of the three economic measures in paragraph (a)(3)(i) of this section.

(4) The hospital bed size risk adjustment factor uses four variables based on the CJR-X participant's characteristics:

- (i) 250 beds or fewer.
- (ii) 251–500 beds.
- (iii) 501–850 beds.
- (iv) 850 beds or more.

(5) The safety net hospital risk adjustment factor is based on the CJR-X participant meeting the safety net hospital definition in § 512.605.

(6) Additional beneficiary level risk adjustment factors represent the presence or absence in beneficiaries, based on a 180-day lookback period that ends on the day prior to the anchor hospitalization or anchor procedure, of each of the following conditions:

(i) Ankle procedure or reattachment, partial hip procedure, partial knee arthroplasty, total hip arthroplasty or hip resurfacing procedure, and total knee arthroplasty.

(ii) Disability as the original reason for Medicare enrollment.

(iii) Prior post-acute care use.

(iv) HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic.

(v) HCC 36: Diabetes with Severe Acute Complications.

(vi) HCC 37: Diabetes with Chronic Complications.

(vii) HCC 48: Morbid Obesity.

(viii) HCC 125: Dementia, Severe.

(ix) HCC 126: Dementia, Moderate.

(x) HCC 127: Dementia, Mild or Unspecified.

(xi) HCC 151: Schizophrenia.

(xii) HCC 155: Major Depression, Moderate or Severe, without Psychosis.

(xiii) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.

(xiv) HCC 224: Acute on Chronic Heart Failure.

(xv) HCC 225: Acute Heart Failure (Excludes Acute on Chronic).

(xvi) HCC 226: Heart Failure, Except End-Stage and Acute.

(xvii) HCC 238: Specified Heart Arrhythmias.

(xviii) HCC 253: Hemiplegia/Hemiparesis.

(xix) HCC 267: Deep Vein Thrombosis and Pulmonary Embolism.

(xx) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.

(xxi) HCC 326: Chronic Kidney Disease, Stage 5.

(xxii) HCC 327: Chronic Kidney Disease, Severe (Stage 4).

(xxiii) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.

(xxiv) HCC 402: Hip Fracture/Dislocation.

(b) *Timing and data used for risk adjustment.* CMS uses 3 years of baseline period data, as described under § 512.640(b)(2)(i) and (ii), to compute all risk adjustment factors prior to the start of the performance year through a linear regression analysis.

(c) *Risk adjustment coefficients.* CMS produces exponentiated coefficients through the annual linear regression analysis to determine the anticipated marginal effect of each risk adjustment factor on episode costs. CMS transforms, or exponentiates, these coefficients, and the resulting coefficients are the beneficiary and hospital-level risk adjustment factors, specified in paragraphs (a)(1) through (6) of this section, that would be used during reconciliation for the subsequent performance year.

(d) *Applying risk adjustment at reconciliation.* At the time of reconciliation, CMS risk adjusts the preliminary target prices calculated under § 512.640 by applying the applicable beneficiary level and hospital-level risk adjustment factors specific to the beneficiary in the episode, as set forth in paragraphs (a)(1) through (6) of this section.

(e) *Normalization factor update.* CMS normalizes the risk-adjusted preliminary target prices at reconciliation so that the average of the

total risk-adjusted preliminary target price does not exceed the average of the total non-risk adjusted preliminary target price.

(1) The final normalization factor at reconciliation—

(i) Is the mean benchmark price for each MS-DRG/HCCPCS episode type and region divided by the mean risk-adjusted benchmark price for the same MS-DRG/HCCPCS episode type and region.

(ii) As applied, cannot exceed +/- 5 percent of the prospective normalization factor (as specified in § 512.640(b)(6)).

(2) CMS applies the final normalization factor to the previously calculated, beneficiary-level, risk-adjusted target prices specific to each region and MS-DRG/HCCPCS episode type.

(f) *Trend factor update.* CMS calculates a multiplier for each MS-DRG/HCCPCS episode type and region which is applied during reconciliation to the most recent calendar year of the applicable baseline period. The multiplier is calculated as the average regional capped performance year episode spending for each MS-DRG/HCCPCS episode type divided by the average regional capped baseline period episode spending for each MS-DRG/HCCPCS episode type.

(1) The retrospective trend factor is capped so that the maximum difference cannot exceed ±3 percent of the prospective trend factor (as specified in § 512.640(b)(7)).

(2) CMS applies the capped retrospective trend factor to the previously calculated normalized, risk-adjusted target prices specific to each region and MS-DRG/HCCPCS episode type, as specified in paragraph (e)(2) of this section.

(g) *Payment system changes.* CMS updates preliminary target prices, as computed under § 512.640, during the construction of reconciliation target prices to account for calendar year and fiscal year payment rule updates that occur after preliminary target prices are constructed.

(h) *Quality adjustment to discount factor.* CMS calculates a composite quality score as specified at § 512.635(b) and adjusts the discount factor specified at § 512.640(b)(8) to calculate the reconciliation target prices, which are compared to performance year spending at reconciliation, as specified in § 512.650(c) as follows:

(1) A CJR-X participant with excellent composite quality scores, defined as composite quality scores greater than or equal to 17.1, receives a 0.0 discount factor.

(2) A CJR-X participant with good composite quality scores, defined as composite quality scores greater than or equal to 12.1 and less than or equal to 17.0, receives a 1.0 discount factor.

(3) A CJR-X participant with acceptable composite quality scores, defined as composite quality scores greater than or equal to 6.1 and less than or equal to 12.0, receives a 2.0 discount factor.

(4) A CJR-X participant with below acceptable composite quality scores, defined as composite quality scores less than or equal to 6.0, receives a 2.0 discount factor and are ineligible to receive a reconciliation payment, as specified in § 512.650(d).

**§ 512.650 Reconciliation process and determination of the reconciliation payment or repayment amount.**

(a) *General.* Providers and suppliers furnishing items and services included in the episode bill for such items and services in accordance with existing Medicare rules.

(b) *Reconciliation process.*

(1) Six months after the end of each performance year, CMS performs a reconciliation calculation to establish a reconciliation payment or repayment amount for each CJR-X participant as described in paragraph (c) of this section.

(2) For CJR-X participants that experience a reorganization event in which one or more hospitals reorganize under the CCN of a CJR-X participant, CMS performs both of the following:

(i) Separate reconciliation calculations for each predecessor CJR-X participant for episodes where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the reorganization event.

(ii) Reconciliation calculations for each new or surviving CJR-X participant for episodes where the anchor hospitalization admission or anchor procedure occurred on or after the effective date of the reorganization event.

(c) *Calculation of the Net Payment Reconciliation Amount (NPRA).* CMS compares the reconciliation target prices described in § 512.645 and the CJR-X participant's performance year spending to establish an NPRA for the CJR-X participant for each performance year as follows:

(1) CMS determines the performance year spending for each episode included in the performance year (other than episodes that have been canceled in accordance with § 512.630(b)) for each MS-DRG/HCPCS episode type using

claims data that is available 6 months after the end of the performance year.

(2) CMS calculates and applies the high-cost outlier cap for performance year episode spending by applying the calculation described in § 512.640(b)(4) to performance year episode spending for each MS-DRG/HCPCS episode type.

(3) CMS applies the adjustments specified in § 512.645 to the preliminary target prices computed in accordance with § 512.640 to calculate the reconciliation target prices for each MS-DRG/HCPCS episode type.

(4) CMS aggregates the reconciliation target prices computed in accordance with paragraph (c)(3) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 512.630(b)).

(5) CMS aggregates the adjusted performance year spending amounts determined under paragraph (c)(1) through (2) of this section and subtracts the resulting amount from the aggregated reconciliation target price amount determined under paragraph (c)(3) through (4) of this section.

(6) CMS applies stop-loss and stop-gain limits to the amount computed in paragraph (c)(5) of this section as follows:

(i) *Limitation on loss.* For CJR-X participants, except as provided in paragraph (d)(3) of this section, the repayment amount for a performance year cannot exceed 20 percent of the aggregated reconciliation target price amount calculated in paragraph (c)(4) of this section for the performance year. The post-episode spending calculation amount in paragraph (c)(7) of this section is not subject to the limitation on loss.

(ii) *Limitation on gain.* For CJR-X participants, the reconciliation payment amount for a performance year cannot exceed 20 percent of the aggregated reconciliation target price amount calculated in accordance with paragraph (c)(4) of this section for the performance year. The post-episode spending amount calculated in accordance with paragraph (c)(7) of this section is not subject to the limitation on gain.

(iii) *Additional limitation on loss for certain hospitals.* The repayment amount for the following types of CJR-X participants as defined at § 512.605, cannot exceed 5 percent of the aggregated reconciliation target price amount calculated in accordance with paragraph (c)(4) of this section:

- (A) Medicare-dependent, small rural hospital (MDH).
- (B) Rural hospital.
- (C) Safety net hospital.
- (D) Sole community hospital (SCH).

(7) CMS calculates the post-episode spending amount. If the average post-episode spending amount for a CJR-X participant in the performance year being reconciled is greater than 3 standard deviations above the regional average post-episode spending amount for the performance year, then the post-episode spending amount that exceeds 3 standard deviations above the regional average post-episode spending amount for the performance year is subtracted from the NPRA for that performance year.

(d) *Reconciliation payment or repayment amount.*

(1) Excluding CJR-X participants that receive a below acceptable composite quality score, as specified in § 512.645(h), if the amount calculated in paragraph (c) of this section is positive, the CJR-X participant is owed a reconciliation payment in that amount, to be paid by CMS in one lump sum payment.

(2) If the amount calculated in paragraph (c) of this section is negative, the CJR-X participant will owe that amount as a repayment to CMS.

(e) *CJR-X reconciliation report.* CMS issues each CJR-X participant a CJR-X reconciliation report for the performance year. Each CJR-X reconciliation report contains the following:

(1) The total performance year spending for the CJR-X participant.

(2) The CJR-X participant's reconciliation target prices.

(3) The CJR-X participant's reconciliation amount.

(4) The CJR-X participant's composite quality score calculated in accordance with § 512.635(b).

(5) The CJR-X participant's quality-adjusted reconciliation amount.

(6) The stop-loss and stop-gain limits that apply to the CJR-X participant.

(7) The CJR-X participant's NPRA.

(8) The CJR-X participant's post-episode spending amount, if applicable.

(9) The amount of any reconciliation payment owed to the CJR-X participant or repayment owed by the CJR-X participant to CMS for the performance year, if applicable.

**§ 512.652 Treatment of incentive programs or add-on payments under existing Medicare payment systems.**

The CJR-X does not replace any existing Medicare incentive programs or add-on payments. The CJR-X payments are independent of, and do not affect, any incentive programs or add-on payments under existing Medicare payment systems.

**§ 512.655 Proration of payments for services that extend beyond an episode.**

(a) *General.* CMS prorates services included in the episode that extend beyond the episode so that only those portions of the services that were furnished during the episode are included in the calculation of the actual episode payments.

(b) *Proration of services.* CMS prorates payments for services that extend beyond the episode for the purposes of calculating both baseline episode spending and performance year spending using the following methodology:

(1) *Non-IPPS inpatient services.* Non-IPPS inpatient services that extend beyond the end of the episode are prorated according to the percentage of the actual length of stay (in days) that falls within the episode.

(2) *Home health agency services.* Home health agency services paid under the Medicare prospective payment system in accordance with part 484, subpart E of this chapter that extend beyond the episode are prorated according to the percentage of days, starting with the first billable service date and through and including the last billable service date, that occur during the episode.

(3) *IPPS services.* IPPS services that extend beyond the end of the episode are prorated according to the MS-DRG geometric mean length of stay, using the following methodology:

(i) The first day of the IPPS stay is counted as 2 days.

(ii) If the actual length of stay that occurred during the episode is equal to or greater than the MS-DRG geometric mean, the full MS-DRG payment is allocated to the episode.

(iii) If the actual length of stay that occurred during the episode is less than the MS-DRG geometric mean length of stay, the MS-DRG payment amount is allocated to the episode based on the number of inpatient days that fall within the episode.

(4) If the full amount of the payment is not allocated to the episode, any remainder amount is allocated to the post-episode spending calculation (defined in § 512.650(c)(7)).

**§ 512.660 Appeals process.**

(a) *General.* Subject to the limitations on review in § 512.170, the CJR-X participant may submit a notice of calculation error for one or more calculations involving a matter related to payment, reconciliation amounts, repayment amounts, the use of quality measure results in determining the composite quality score, or the

application of the composite quality score during reconciliation.

**(b) Requirements.**

(1) If the CJR-X participant identifies a calculation error as described in paragraph (a) of this section, the CJR-X participant must submit written notice of the error, in a form and manner specified by CMS, within 30 days of the issuance of the reconciliation report.

(2) If the CJR-X participant does not provide timely written notice of calculation error, CMS deems the CJR-X reconciliation report to be final 30 days after it is issued and proceeds with the payment or repayment processes as applicable.

(3) Only CJR-X participants may use the calculation error process described in this part.

**(c) Process.**

(1) If CMS determines the timely error notice meets the requirements of this section and contains sufficient information to substantiate the request, CMS issues an initial determination in writing within 30 days of receipt to either confirm that there was an error in the calculation or verify that the calculation is correct.

(2) CMS reserves the right to extend the time for providing its initial final determination upon written notice to the CJR-X participant.

(3) If the request is not compliant with the requirements of this section or requires additional information—

(i) CMS contacts the CJR-X participant to request additional information in a form and manner as specified by CMS;

(ii) The CJR-X participant must respond within 10 days of CMS' request for additional information in a form and manner as specified by CMS; and

(iii) If a CJR-X participant does not respond in accordance with paragraph (c)(3)(ii) of this section, then the reconciliation report is deemed final.

(d) *Reconsideration request.* A CJR-X participant who wishes to dispute an initial determination made in accordance with paragraph (c) of this section may invoke the reconsideration review process under § 512.190.

**Data Sharing****§ 512.665 Data sharing with CJR-X participants.**

(a) *General.* CMS shares certain beneficiary-identifiable data as described in paragraphs (b), (c), and (e) of this section and certain regional aggregate data as described in paragraph (d) of this section with CJR-X participants regarding CJR-X beneficiaries and performance under the model.

(b) *Beneficiary-identifiable claims data.* CMS shares beneficiary-identifiable claims data with CJR-X participants as follows:

(1) CMS makes available certain beneficiary-identifiable claims data described in paragraph (5) of this section for CJR-X participants to request for purposes of conducting health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 regarding their CJR-X beneficiaries.

(2) A CJR-X participant that wishes to receive beneficiary-identifiable claims data for its CJR-X beneficiaries must:

(i) Submit a formal request for the data on an annual basis in a manner and form and by a date specified by CMS, indicating their selection of summary beneficiary-identifiable data, raw beneficiary-identifiable data, or both, and attest that—

(A) The CJR-X participant is requesting claims data of CJR-X beneficiaries who would be in an episode during the baseline period or performance year, as a HIPAA covered entity.

(B) The CJR-X participant's request reflects the minimum data necessary, as set forth in paragraph (c) of this section, for the CJR-X participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(C) The CJR-X participant's use of claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care, improving the quality and efficiency of care, and conducting population-based activities relating to improving health or reducing health care costs that are applied uniformly to all CJR-X beneficiaries, in an episode during the baseline period or performance year, and that these data will not be used to reduce, limit or restrict care for specific Medicare beneficiaries.

(ii) Sign and submit a CJR-X data sharing agreement, as defined in § 512.605, with CMS as set forth in paragraph (e) of this section.

(3) CMS shares this beneficiary-identifiable claims data with a CJR-X participant in accordance with applicable privacy and security laws and established privacy and security protections.

(4) CMS omits from the beneficiary-identifiable claims data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable claims data will include, when available, the following:

(i) Unrefined (raw) Medicare Parts A and B beneficiary-identifiable claims data for CJR-X beneficiaries in an episode during the 3-year baseline period and performance year.

(ii) Summarized (summary) Medicare Parts A and B beneficiary-identifiable claims data for CJR-X beneficiaries in an episode during the 3-year baseline period and applicable performance year.

(6) CMS makes available the beneficiary-identifiable claims data for retrieval by CJR-X participants at the following frequency:

(i) Annually, at least one month prior to every performance year for baseline period data, based on the baseline periods described in § 512.640(b)(2).

(ii) As frequently as monthly during the performance year and for up to 6 months after the performance year for performance year data.

(c) *Minimum necessary data.* The CJR-X participant must limit its request for beneficiary-identifiable data under paragraph (b) of this section to the minimum necessary Parts A and B data elements which may include, but are not limited to the following:

- (1) Medicare beneficiary identifier (ID).
- (2) Procedure code.
- (3) Sex.
- (4) Diagnosis code.
- (5) Claim ID.
- (6) The from and through dates of service.

(7) The provider or supplier ID.

(8) The claim payment type.

(9) Date of birth and death, if applicable.

(10) Tax identification number.

(11) National provider identifier.

(d) *Regional aggregate data.*

(1) CMS shares regional aggregate data for the 3-year baseline period and relevant performance year with CJR-X participants as follows.

(i) CMS shares 3-year baseline period regional aggregate data annually at least 1 month before the relevant performance year, based on the baseline periods described in § 512.640(b)(2).

(ii) CMS shares performance year regional aggregate data as frequently as a monthly basis during the applicable performance year and for up to 6 months after the relevant performance year.

(2) Regional aggregate data will—

(i) Be aggregated based on all Parts A and B claims associated with episodes in CJR-X for the U.S. Census Division in which the CJR-X participant is located;

(ii) Summarize average episode spending for episodes in CJR-X in the

U.S. Census Division in which the CJR-X participant is located; and

(iii) Be de-identified in accordance with 45 CFR 164.514(b).

(e) *CJR-X data sharing agreement.*

(1) A CJR-X participant who wishes to retrieve the beneficiary-identifiable data specified in paragraph (b) of this section, must complete and submit, on at least an annual basis, a signed CJR-X data sharing agreement, as defined in § 512.605, to be provided in a form and manner and by a date specified by CMS, under which the CJR-X Participant agrees:

(i) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA Privacy Rule (45 CFR part 160 and subparts A and E of part 164) and the requirements of the CJR-X set forth in this part.

(ii) To comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the CJR-X data sharing agreement.

(iii) To contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the CJR-X participant to the same terms and conditions to which the CJR-X participant is itself bound in its CJR-X data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the CJR-X participant under the CJR-X.

(iv) That if the CJR-X participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may deem the CJR-X participant ineligible to retrieve beneficiary-identifiable data under paragraph (b) of this section for any amount of time, and the CJR-X participant may be subject to additional sanctions and penalties available under the law.

(2) A CJR-X participant must comply with all applicable laws and the terms of the CJR-X data sharing agreement in order to retrieve the beneficiary-identifiable data.

#### **Financial Arrangements and Beneficiary Incentives**

##### **§ 512.670 Sharing arrangements.**

(a) *General.*

(1) A CJR-X participant may enter into a sharing arrangement with a CJR-X collaborator to make a gainsharing payment, or to receive an alignment

payment, or both. A CJR-X participant must not make a gainsharing payment to a CJR-X collaborator or receive an alignment payment from a CJR-X collaborator except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) CJR-X participants must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR-X collaborators.

(i) These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential CJR-X collaborator and the provision of CJR-X activities.

(ii) The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the CJR-X participant, any CJR-X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR-X participant, CJR-X collaborator, collaboration agent, or downstream collaboration agent.

(iii) A selection criterion that considers whether a potential CJR-X collaborator has performed a reasonable minimum number of services that would qualify as CJR-X activities, as determined by the CJR-X participant, will be deemed not to violate the volume or value standard if the purpose of the criterion is to ensure the quality of care furnished to CJR-X beneficiaries.

(4) If a CJR-X participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of CJR-X.

(b) *Requirements.*

(1) A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to CJR-X beneficiaries under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) The sharing arrangement must require the CJR-X collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with all of the following:

(i) The applicable provisions of this part 512 (including requirements regarding beneficiary notifications in



§ 512.622, access to records in § 512.135(b), record retention in § 512.135(c), and participation in any evaluation, monitoring, compliance in § 512.130, and enforcement activities performed by CMS or its designees in § 512.160).

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the CJR–X collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of CJR–X that apply to its role as a CJR–X collaborator, including any distribution arrangements.

(5) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(6) The board or other governing body of the CJR–X participant must have responsibility for overseeing the CJR–X participant's participation in CJR–X, its arrangements with CJR–X collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the CJR–X model.

(7) The specifics of the agreement must be documented in writing and must be made available to CMS upon request (as outlined in § 512.150).

(8) The sharing arrangement must specify the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The obligations of the parties, including specified CJR–X activities and other services to be performed by the parties under the sharing arrangement.

(iii) The date range for which the sharing arrangement is effective.

(iv) The financial or economic terms for payment, including the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payments.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment or alignment payment.

(9) The sharing arrangement must not do either of the following:

(i) Induce the CJR–X participant, CJR–X collaborator, or any employees, contractors, or subcontractors of the CJR–X participant or CJR–X collaborator to reduce or limit medically necessary services to any Medicare beneficiary.

(ii) Restrict the ability of a CJR–X collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) *Gainsharing payment, alignment payment, and internal cost savings conditions and restrictions.*

(1) Gainsharing payments, if any, must—

(i) Be derived solely from reconciliation payment amounts, or internal cost savings, or both;

(ii) Be distributed on an annual basis (not more than once per calendar year);

(iii) Not be a loan, advance payment, or payment for referrals or other business; and

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2) Gainsharing payment eligibility—

(i) To be eligible to receive a gainsharing payment, a CJR–X collaborator must meet quality of care criteria for the performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality-of-care criteria must be established by the CJR–X participant and directly relate to the episode.

(ii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR–X collaborator other than ACO, PGP, NPPGP, or TGP must have directly furnished a billable item or service to a CJR–X beneficiary during an episode that was attributed to the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment.

(iii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR–X collaborator that is a PGP, NPPGP, or TGP must meet the following criteria:

(A) The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively to a CJR–X beneficiary during an episode that was attributed to the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment.

(B) The PGP, NPPGP, or TGP must have contributed to CJR–X activities and been clinically involved in the care of CJR–X beneficiaries during the same

performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment. A non-exhaustive list of examples where, a PGP, NPPGP, or TGP might have been clinically involved in the care of CJR–X beneficiaries includes—

(1) Providing care coordination services to CJR–X beneficiaries during or after inpatient admission;

(2) Engaging with a CJR–X participant in care redesign strategies, and performing a role in implementing such strategies, that are designed to improve the quality of care for episodes and reduce episode spending; or

(3) In coordination with other providers and suppliers (such as PGP members, NPPGP members, or TGP members; the CJR–X participant; and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR–X beneficiaries.

(iv) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR–X collaborator that is an ACO must meet the following criteria:

(A) The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to a CJR–X beneficiary during an episode that was attributed to the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment; and

(B) The ACO must have contributed to CJR–X activities and been clinically involved in the care of CJR–X beneficiaries during the performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment. A non-exhaustive list of ways in which an ACO might have been clinically involved in the care of CJR–X beneficiaries could include—

(1) Providing care coordination services to CJR–X beneficiaries during and/or after inpatient admission;

(2) Engaging with a CJR–X participant in care redesign strategies and performing a role in implementing such strategies that are designed to improve the quality of care and reduce spending for episodes; or

(3) In coordination with providers and suppliers (such as ACO participants,



ACO providers/suppliers, the CJR–X participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR–X beneficiaries.

(3) The methodology for accruing, calculating and verifying internal cost savings will be determined by the CJR–X participant. The methodology—

(i) Must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(ii) Used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the CJR–X participant through the documented implementation of CJR–X activities identified by the CJR–X participant and must exclude—

(A) Any savings realized by any individual or entity that is not the CJR–X participant; and

(B) “Paper” savings from accounting conventions or past investment in fixed costs.

(4) The amount of any gainsharing payments must be determined in accordance with a methodology that is based solely on quality of care and the provision of CJR–X activities. The methodology may take into account the amount of CJR–X activities provided by a CJR–X collaborator relative to other CJR–X collaborators.

(5) For a performance year, the aggregate amount of all gainsharing payments that are derived from reconciliation payment amounts must not exceed the amount of that year’s reconciliation payment amount.

(6) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent.

(7) A CJR–X participant must not make a gainsharing payment to a CJR–X collaborator if CMS has notified the CJR–X participant that such CJR–X collaborator is subject to any action by CMS, HHS or any other governmental entity, or its designees, for noncompliance with this part or the fraud and abuse laws, for the provision of substandard care to CJR–X beneficiaries or other integrity

problems, or for any other program integrity problems or noncompliance with any other laws or regulations.

(8) The sharing arrangement must require the CJR–X participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation payment amount or was based on the submission of false or fraudulent data.

(9) Alignment payments from a CJR–X collaborator to a CJR–X participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a repayment amount;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by a CJR–X participant in the absence of a repayment amount.

(10) The CJR–X participant must not receive any amounts under a sharing arrangement from a CJR–X collaborator that are not alignment payments.

(11) For a performance year, the aggregate amount of all alignment payments received by the CJR–X participant must not exceed 50 percent of the CJR–X participant’s repayment amount.

(12) The aggregate amount of all alignment payments from a CJR–X collaborator to the CJR–X participant may not be greater than with respect to a CJR–X collaborator—

(i) Other than an ACO, 25 percent of the CJR–X participant’s repayment amount; or

(ii) That is an ACO, 50 percent of the CJR–X participant’s repayment amount.

(13) The amount of any alignment payments must be determined in accordance with a methodology that does not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent.

(14) All gainsharing payments and any alignment payments must be administered by the CJR–X participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(15) All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(d) *Documentation requirements.*

(1) CJR–X participants must—

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement;

(ii) Post (and update on at least a quarterly basis) on a publicly available web page on the CJR–X participant’s website the following:

(A) Accurate lists of all current CJR–X collaborators, including the CJR–X collaborators’ names and addresses as well as accurate historical lists of all CJR–X collaborators.

(B) Written policies for selecting individuals and entities to be CJR–X collaborators as required by § 512.670(a)(3).

(iii) Maintain, and require each CJR–X collaborator to maintain, contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes all of the following, at a minimum:

(A) Nature of the payment (gainsharing payment or alignment payment).

(B) Identity of the parties making and receiving the payment.

(C) Date of the payment.

(D) Amount of the payment.

(E) Date and amount of any recoupment of all or a portion of a CJR–X collaborator’s gainsharing payment.

(F) Explanation for each recoupment, such as whether the CJR–X collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of a reconciliation payment or was based on the submission of false or fraudulent data.

(2) The CJR–X participant must keep records of all of the following:

(i) A process for determining and verifying its potential and current CJR–X collaborators’ eligibility to participate in Medicare.

(ii) A plan to track internal cost savings.

(iii) Information on the accounting systems used to track internal cost savings.

(iv) A description of current health information technology, including systems to track reconciliation payment amounts, repayment amounts, and internal cost savings.

(v) A plan to track gainsharing payments and alignment payments.

(3) The CJR–X participant must retain and provide access to, and require each CJR–X collaborator to retain and provide access to, the required documentation in accordance with § 512.135.

#### **§ 512.675 Distribution arrangements.**

(a) *General.*

(1) An ACO, PGP, NPPGP, or TGP that is a CJR–X collaborator and has entered

into a sharing arrangement with a CJR-X participant may distribute all or a portion of any gainsharing payment it receives from the CJR-X participant only in accordance with a distribution arrangement.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

*(b) Requirements.*

(1) All distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to CJR-X beneficiaries under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the CJR-X participant, any CJR-X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR-X participant, CJR-X collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any distribution payments from an ACO, from an NPPGP to an NPPGP member, or from a TGP to a TGP member, must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR-X activities and that may take into account the amount of such CJR-X activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR-X activities and that may take into account the amount of such CJR-X activities provided by a collaboration agent relative to other collaboration agents.

(7) A collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to a CJR-X beneficiary during an episode that was attributed to the same performance year for which the CJR-X participant accrued the internal cost savings or earned the reconciliation

payment amount that comprises the gainsharing payment being distributed.

(8) With respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP, or TGP, the total amount of all distribution payments for a performance year must not exceed the amount of the gainsharing payment received by the CJR-X collaborator from the CJR-X participant for the same performance year.

(9) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(11) The distribution arrangement must not do either of the following:

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary.

(ii) Reward the provision of items and services that are medically unnecessary.

(12) The CJR-X collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.135, including all of the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s).

(iii) The identity of each collaboration agent that received a distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(13) The CJR-X collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same CJR-X participant.

(14) The CJR-X collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.135.

**§ 512.680 Downstream distribution arrangements.**

*(a) General.*

(1) An ACO participant that is a PGP, NPPGP, or TGP and that has entered into a distribution arrangement with a CJR-X collaborator that is an ACO, may distribute all or a portion of any distribution payment it receives from the CJR-X collaborator only in accordance with a downstream distribution arrangement.

(2) All downstream distribution arrangements must comply with the provisions of this section and all

applicable laws and regulations, including the fraud and abuse laws.

*(b) Requirements.*

(1) All downstream distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to CJR-X beneficiaries under the downstream distribution arrangement.

(2) Participation in a downstream distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the CJR-X participant, any CJR-X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR-X participant, CJR-X collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any downstream distribution payments from an NPPGP to an NPPGP member or from a TGP to a TGP member must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR-X activities and that may take into account the amount of such CJR-X activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(6) The amount of any downstream distribution payments from a PGP must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR-X activities and that may take into account the amount of such CJR-X activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(7) A downstream collaboration agent is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service to a CJR-X beneficiary during an episode that is attributed to the same performance year for which the CJR-X participant accrued the internal cost savings or earned the reconciliation payment amount that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP,

NPPGP, or TGP that is an ACO participant.

(8) The total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the PGP, NPPGP, or TGP from the ACO.

(9) All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The downstream collaboration agent must retain his or her ability to make decisions in the best interests of the beneficiary, including the selection of devices, supplies, and treatments.

(11) The downstream distribution arrangement must not do either of the following:

(i) Induce the downstream collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary.

(ii) Reward the provision of items and services that are medically unnecessary.

(12) The PGP, NPPGP, or TGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.135, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any downstream distribution payment.

(iii) The identity of each downstream collaboration agent that received a downstream distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

(13) The PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP member, NPPGP member, or TGP member who has—

(i) A sharing arrangement with a CJR–X participant.

(ii) A distribution arrangement with the ACO that the PGP, NPPGP, or TGP is a participant in.

(14) The PGP, NPPGP, or TGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.135.

#### **§ 512.685 CJR–X beneficiary incentives.**

(a) *General.* CJR–X participants may choose to provide in-kind patient engagement incentives including but not limited to items of technology to CJR–X beneficiaries in an episode, subject to the following conditions:

(1) The incentive must be provided directly by the CJR–X participant or by an agent of the CJR–X participant under the CJR–X participant's direction and

control to the CJR–X beneficiary during an episode.

(2) The item or service provided must be reasonably connected to medical care provided to a CJR–X beneficiary during an episode.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (c) of this section, for a CJR–X beneficiary in an episode by engaging the CJR–X beneficiary in better managing his or her own health.

(4) The item or service must not be tied to the receipt of items or services outside the episode.

(5) The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

(6) The availability of the items or services must not be advertised or promoted, except that a CJR–X beneficiary may be made aware of the availability of the items or services at the time the CJR–X beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to any federal health care program, as defined at section 1128B(f) of the Act.

(b) *Technology provided to a CJR–X beneficiary.* CJR–X beneficiary engagement incentives involving technology are subject to the following additional conditions:

(1) Items or services involving technology provided to a CJR–X beneficiary may not exceed \$1,000 in retail value for any one CJR–X beneficiary during any one episode.

(2) Items or services involving technology provided to a CJR–X beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (c) of this section, for a beneficiary in an episode.

(3) Items of technology exceeding \$75 in retail value must—

(i) Remain the property of the CJR–X participant; and

(ii) Be retrieved from the CJR–X beneficiary at the end of the episode, with documentation of the ultimate date of retrieval. The CJR–X participant must document all retrieval attempts. In cases when the item of technology is not able to be retrieved, the CJR–X participant must determine why the item was not retrievable. If it was determined that the item was misappropriated (if it were sold, for example), the CJR–X participant must take steps to prevent future beneficiary incentives for that CJR–X beneficiary. Following this process, documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(c) *Clinical goals of CJR–X.* The following are the clinical goals of CJR–X, which may be advanced through CJR–X beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to a care plan.

(3) Reduction of readmissions and complications following an episode.

(4) Management of chronic diseases and conditions that may be affected by the CJR–X procedure.

(d) *Documentation of CJR–X beneficiary incentives.*

(1) CJR–X participants must maintain documentation of items and services furnished as beneficiary incentives that exceed \$25 in retail value.

(2) The documentation must be established contemporaneously with the provision of the items and services with a record established and maintained to include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the CJR–X beneficiary to whom the item or service was provided.

(3) The documentation regarding items of technology exceeding \$75 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of an episode, or why the items were not retrievable, as described in paragraph (b)(3) of this section.

(4) The CJR–X participant must retain and provide access to the required documentation in accordance with § 512.135.

#### **§ 512.690 Application of the CMS-sponsored Model Arrangements and Patient Incentives Safe Harbor.**

(a) *Application of the CMS-sponsored model arrangements safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) is available to protect remuneration furnished in CJR–X in the form of the sharing arrangement's gainsharing payments and alignment payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and § 512.670, in the form of the distribution arrangement's distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and § 512.675, and in the form of the downstream distribution arrangement's distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and § 512.680.

(b) *Application of the CMS-sponsored model patient incentives safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for

CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect CJR–X beneficiary incentives that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and 512.685

### Medicare Program Waivers

#### § 512.695 CJR–X Medicare Program Waivers.

(a) *Waiver of certain telehealth requirements.*

(1) *Waiver of the geographic site requirements.* Except for the geographic site requirements for a face-to-face encounter for home health certification, CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for episodes being tested in CJR–X solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are included in the episode in accordance with § 512.625(e).

(2) *Waiver of the originating site requirements.* Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (X) of the Act for episodes to permit a telehealth visit to originate in the beneficiary's home or place of residence solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are included in the episode in accordance with § 512.625(e).

(3) *Waiver of selected payment provisions.*

(i) CMS waives the payment requirements under section 1834(m)(2)(B) of the Act so that the facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home or place of residence.

(ii) CMS waives the payment requirements under section 1834(m)(2)(A) of the Act to allow the distant site payment for telehealth home visit HCPCS codes unique to CJR–X.

(4) *Other requirements.* All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

(b) *Waiver of the SNF 3-day rule.*

(1) *Episodes initiated by an anchor hospitalization.* CMS waives the SNF 3-day rule for coverage of a SNF stay within 90 days of the date of discharge

from the anchor hospitalization for a beneficiary who is a CJR–X beneficiary on the date of discharge from the anchor hospitalization if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR–X beneficiary's admission to the SNF.

(2) *Episodes initiated by an anchor procedure.* CMS waives the SNF 3-day rule for coverage of a SNF stay within 90 days of the date of service of the anchor procedure for a beneficiary who is a CJR–X beneficiary on the date of service of the anchor procedure if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR–X beneficiary's admission to the SNF.

(3) *Determination of qualified SNFs.* CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website.

(i) Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months.

(ii) Qualified SNFs include providers furnishing SNF services under swing bed agreements, which will not be subject to the star ratings requirement.

(4) *Posting of qualified SNFs.* CMS posts to the CMS website the list of qualified SNFs in advance of the calendar quarter.

(5) *Financial liability for non-covered SNF services.* If CMS determines that the waiver requirements specified in paragraph (b) of this section were not met, the following apply:

(i) CMS makes no payment to a SNF for SNF services if the SNF admits a CJR–X beneficiary who has not had a qualifying anchor hospitalization or anchor procedure.

(ii) In the event that CMS makes no payment for SNF services furnished by a SNF as a result of paragraph (b)(5)(i) of this section, the beneficiary protections specified in paragraph (b)(5)(iii) of this section apply, unless the CJR–X participant has provided the beneficiary with a discharge planning notice in accordance with § 512.622(c).

(iii) If the CJR–X participant does not provide the beneficiary with a discharge planning notice in accordance with § 512.622(c)—

(A) The SNF must not charge the beneficiary for the expenses incurred for such services;

(B) The SNF must return to the beneficiary any monies collected for such services; and

(C) The CJR–X participant is financially liable for the expenses incurred for such services.

(4) If the CJR–X participant provided a discharge planning notice to the beneficiary in accordance with § 512.622(c), then normal SNF coverage requirements apply and the beneficiary may be financially liable for non-covered SNF services.

(6) *Other requirements.* All other Medicare rules for coverage and payment of Part A-covered services continue to apply except as otherwise waived in this part.

(c) *Waiver of direct supervision requirement for certain post-discharge home visits.*

(1) *General.* CMS waives the requirement in § 410.26(b)(5) of this chapter that services and supplies furnished incident to a physician's service must be furnished under the direct supervision of the physician (or other practitioner) to permit home visits as specified in this section. The services furnished under this waiver are not considered to be "hospital services," even when furnished by the clinical staff of the hospital.

(2) *General supervision of qualified personnel.* The waiver of the direct supervision requirement in § 410.26(b)(5) of this chapter applies only in the following circumstances:

(i) The home visit is furnished during the episode to a CJR–X beneficiary who has been discharged from an anchor hospitalization or anchor procedure.

(ii) The home visit is furnished at the CJR–X beneficiary's home or place of residence.

(iii) The CJR–X beneficiary does not qualify for home health services under sections 1835(a) and 1814(a) of the Act at the time of any such home visit.

(iv) The visit is furnished by clinical staff under the general supervision of a physician or non-physician practitioner. Clinical staff are individuals who work under the supervision of a physician or other qualified health care professional, and who are allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but do not individually report that professional service.

(v) No more than 9 visits are furnished to the CJR–X beneficiary during the episode.

(3) *Payment.* Up to 9 post-discharge home visits per CJR–X episode may be billed under Part B by the physician or nonphysician practitioner or by the CJR–X participant to which the supervising physician has reassigned his or her billing rights.

(4) *Other requirements.* All other Medicare rules for coverage and

payment of services incident to a physician's service continue to apply.

**Robert F. Kennedy, Jr.**

*Secretary, Department of Health and Human Services.*

**Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2026, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2026**

**I. Summary and Background**

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2027 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2027. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that would be effective for cost reporting periods beginning on or after October 1, 2026. In addition, we are setting forth a description of the methods and data we used to determine the LTCH PPS standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2027.

In general, except for SCHs and MDHs, for FY 2027, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment:

- The Federal national rate (including, as discussed in section IV.E. of the preamble of this final rule, uncompensated care payments under section 1886(r)(2) of the Act).
- The updated hospital-specific rate based on FY 1982 costs per discharge.
- The updated hospital-specific rate based on FY 1987 costs per discharge.
- The updated hospital-specific rate based on FY 1996 costs per discharge.

- The updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 extended the MDH program through FY 2025. As discussed in section V.F. of the preamble of this proposed rule, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027. We refer readers to section V.F. of the preamble of this proposed rule for further discussion of the MDH program.

As discussed in section V.B.2. of the preamble of this proposed rule, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. In general, Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update. Accordingly, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2027. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2027. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2027. In section V. of this Addendum, we discuss proposed policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2027. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

**II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2027**

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. In this section, we discuss the factors we are proposing to use for determining the prospective payment rates for FY 2027.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2027, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR

user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable

percentage increases that can be applied to the national standardized amount.

We refer readers to section VI.B. of the preamble of this proposed rule for a

complete discussion on the FY 2027 inpatient hospital update. The table that follows shows these four scenarios:

| <b>PROPOSED FY 2027 APPLICABLE PERCENTAGE INCREASE FOR THE IPPS</b>                                           |                                                                     |                                                                         |                                                                          |                                                                              |
|---------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------|
| <b>FY 2027</b>                                                                                                | <b>Hospital Submitted Quality Data and is a Meaningful EHR User</b> | <b>Hospital Submitted Quality Data and is NOT a Meaningful EHR User</b> | <b>Hospital Did NOT Submit Quality Data and is a Meaningful EHR User</b> | <b>Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User</b> |
| <b>Proposed Market Basket Rate-of-Increase</b>                                                                | 3.2                                                                 | 3.2                                                                     | 3.2                                                                      | 3.2                                                                          |
| <b>Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act</b>    | 0.0                                                                 | 0.0                                                                     | -0.8                                                                     | -0.8                                                                         |
| <b>Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act</b> | 0.0                                                                 | -2.4                                                                    | 0.0                                                                      | -2.4                                                                         |
| <b>Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act</b>                            | -0.8                                                                | -0.8                                                                    | -0.8                                                                     | -0.8                                                                         |
| <b>Proposed Applicable Percentage Increase Applied to Standardized Amount</b>                                 | <b>2.4</b>                                                          | <b>0.0</b>                                                              | <b>1.6</b>                                                               | <b>-0.8</b>                                                                  |

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for “subsection (d)” hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico. In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users for FY 2027 and subsequent fiscal years is adjusted by the proposed adjustment for failure to be a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act. The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.

- An adjustment to the standardized amount to ensure budget neutrality for the permanent 10-percent cap on the reduction in a MS–DRG’s relative

weight in a given fiscal year, as discussed in section II.D.2.c. of the preamble of this proposed rule, consistent with our current methodology for implementing DRG recalibration and reclassification budget neutrality under section 1886(d)(4)(C)(iii) of the Act.

- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005)). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.

- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2026 budget neutrality factor and applying a revised factor.

- An adjustment to the standardized amount to implement in a budget neutral manner the wage index cap policy (as described in section III.G.5 of the preamble of this proposed rule).

- Using our authority under section 1886(d)(5)(I)(i) of the Act, an adjustment to the standardized amount to implement in a budget neutral manner the transition for the discontinuation of the low wage index hospital policy (as described in section III.F.6 of the preamble of this proposed rule).

- An adjustment to remove the FY 2026 outlier offset and apply an offset for FY 2027, as provided for in section 1886(d)(3)(B) of the Act.

We note, in section VI.N. of the preamble of this proposed rule, we discuss the Rural Community Hospital Demonstration (RCHD) program. In past years, we made an adjustment to ensure the effects of the RCHD program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. As discussed in that section, as we are not yet able to finalize the FY 2027 estimated costs of the demonstration at this time, we are not proposing to apply a budget neutrality offset in this FY 2027 IPPS/LTCH PPS proposed rule. Rather, we are proposing to apply budget neutrality offsets for both FY 2027 and FY 2028 to the national IPPS rates in the FY 2028 IPPS/LTCH PPS rulemaking. We would also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration. We refer the reader to section VI.N. of the preamble of this proposed rule for complete details on this proposal.

For FY 2027, consistent with current law, we are proposing to apply the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the FY 2027 wage index for the rural floor.

For FY 2027, we are proposing to continue to not remove the Stem Cell Acquisition Budget Neutrality Factor from the prior year's standardized amount and to not apply a new factor. If we removed the prior year's adjustment, we would not satisfy budget neutrality. We believe this approach ensures the effects of the reasonable cost-based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) are budget neutral as required under section 108 of Public Law 116–94. For a discussion of Stem Cell Acquisition Budget Neutrality Factor, we refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59032 and 59033).

#### *A. Calculation of the Proposed Adjusted Standardized Amount*

##### **1. Standardization of Base-Year Costs or Target Amounts**

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983, interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2027, we are proposing to continue to use the national labor-related and nonlabor-related shares (which are based on the 2023-based hospital IPPS market basket) that were used in FY 2026. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to

wages and wage-related costs as the "labor-related share." For FY 2027, as discussed in section III.H. of the preamble of this proposed rule, we are proposing to use a labor-related share of 66.0 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the internet on the CMS website.

##### **2. Computing the National Average Standardized Amount**

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage increase. Accordingly, we are proposing to calculate the FY 2027 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

##### **3. Updating the National Average Standardized Amount**

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, we are proposing to use the 2023-based IPPS operating and capital market baskets for FY 2027. As discussed in section VI.B. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2027 applicable percentage increase (which for this proposed rule is based on IGI's fourth quarter 2025 forecast of the 2023-based IPPS market basket) by the productivity adjustment, as discussed elsewhere in this proposed rule.

Based on IGI's fourth quarter 2025 forecast of the IPPS hospital market basket percentage increase (as discussed in appendix B of this proposed rule), the forecast of the hospital market basket percentage increase for FY 2027 for this proposed rule is 3.2 percent and the

forecast of the productivity adjustment for FY 2027 for this proposed rule is 0.8 percentage point. As discussed earlier, for FY 2027, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section VI.B. of the preamble of this proposed rule for a complete discussion on the proposed FY 2027 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four possible applicable percentage increases that would be applied to update the national standardized amounts. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2027 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2027 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the proposed FY 2027 update factors is set forth in appendix B of this proposed rule.

##### **4. Methodology for Calculation of the Average Standardized Amount**

The methodology we used to calculate the proposed FY 2027 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf>); exclude CAHs and Rural Emergency Hospitals (REHs) at the time of this proposed rule (we finalized to remove REHs in the calculation of the standardized amount in the FY 2025 IPPS/LTCH final rule (89 FR 69941–69942); exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS excluded-



cancer hospitals that have a “V” in the fifth position of their provider number or a “E” or “F” in the sixth position.

- As in the past, we are proposing to adjust the FY 2027 standardized amount to remove the effects of the FY 2027 geographic reclassifications and outlier payments before applying the FY 2027 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2027 payment policies.

- We do not remove the prior year’s budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year’s adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total “operating DRG payments,” which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

- Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a “Claim Type” of 60 (which is a field on the MedPAR

file that indicates a claim is an FFS claim).

- Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a “GHOPAD” indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of “3” for blood clotting with a revenue code of “0636” from the covered charge field for the budget neutrality adjustments. We are removing organ acquisition charges, except for cases that group to MS–DRG 018, from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS. Revenue centers 081X–089X are typically excluded from ratesetting, however, we are not removing revenue center 891 charges from MS–DRG 018 claims during ratesetting because those revenue 891 charges were included in the relative weight calculation for MS–DRG 018, which is consistent with the policy finalized in the FY 2021 final rule (85 FR 58600). We note that a new MedPAR variable for revenue code 891 charges was introduced in April 2020.

- For FY 2027, we are continuing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).

- Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects

the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2027, we are proposing to continue to apply a proxy based on the prior fiscal year hospital readmissions payment adjustment and a proxy based on the prior fiscal year hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). Under this proposed policy for FY 2027, we used the final FY 2026 readmissions adjustment factors from Table 15 of the FY 2026 IPPS/LTCH PPS final rule and the final FY 2026 hospital VBP adjustment factors from Table 16B of the FY 2026 IPPS/LTCH PPS final rule. These proxy factors are applied on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum. We refer the reader to section V.K. of the preamble of this proposed rule for a complete discussion on the Hospital Readmissions Reduction Program and section V.L. of the preamble of this proposed rule for a complete discussion on the Hospital VBP Program.

- The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate



payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

Consistent with prior fiscal years, we are proposing to include the estimated empirically justified Medicare DSH payments that would be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

We also are including the estimated supplemental payments for eligible IHS/ Tribal hospitals and Puerto Rico hospitals on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

- When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.G. of the preamble to this proposed rule and later in this section, we are proposing to continue to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

As discussed elsewhere in this proposed rule, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027. For this proposed rule, approximately 80 hospitals would receive additional payments under the MDH program for the first quarter of FY 2027. Given the limited magnitude, we are proposing not to include this extension in the total payments for budget neutrality. Therefore, for purposes of this proposed rule's calculations, we computed payments under the Federal national rate (not

including 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate as applicable) for the total payments for these hospitals in the budget neutrality calculations discussed in this section and we accounted for uncompensated care payments in the computation of total payments under the Federal rate.

- We are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2027. Similar to FY 2026, we are including this adjustment based on data on the prior year's performance. Payments for hospitals would be estimated based on the applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2027.

- In our determination of all budget neutrality factors described in section II.A.4. of this Addendum, we used transfer-adjusted discharges.

We note, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49414 through 49415), we finalized a change to the ordering of the budget neutrality factors in the calculation so that the RCH Demonstration budget neutrality factor (if applicable to the fiscal year) is applied after all wage index and other budget neutrality factors. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

#### a. Proposed Reclassification and Recalibration of MS–DRG Relative Weights Before Cap

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.D. of the preamble of this proposed rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For this FY 2027 proposed rule, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2025 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2026 labor-related share percentages, the FY 2026 relative weights, and the FY 2026 pre-reclassified wage data, and applied the proxy hospital readmissions payment adjustments and proxy hospital VBP payment adjustments (as described previously); and

- Aggregate payments using the FY 2026 labor-related share percentages, the proposed FY 2027 relative weights before applying the 10-percent cap, and the FY 2026 pre-reclassified wage data, and applied the same proxy hospital readmissions payment adjustments and proxy hospital VBP payment adjustments applied previously.

Because this payment simulation uses the proposed FY 2027 relative weights (before applying the 10-percent cap), consistent with our policy in section V.I. of the preamble to this proposed rule, we are applying the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2027 relative weights, we are proposing to apply the adjustor for certain MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and other immunotherapies) cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section V.I. of the preamble of this proposed rule for a complete discussion on the proposed adjustor for certain cases that group to MS–DRG 018 and to section II.D.2.b. of the preamble of this proposed rule, for a complete discussion of the proposed adjustment to the FY 2027 relative weights to account for certain cases that group to MS–DRG 018.

Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are proposing to apply the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2026. Please see the table later in this section setting forth each of the proposed FY 2027 budget neutrality factors.

**b. Proposed Budget Neutrality Adjustment for Reclassification and Recalibration of MS–DRG Relative Weights With Cap**

As discussed in section II.D.2.c. of the preamble of this proposed rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900), we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. As also discussed in section II.D.2.c. of the preamble of this proposed rule, and consistent with our current methodology for implementing budget neutrality for MS–DRG reclassification and recalibration of the relative weights under section 1886(d)(4)(C)(iii) of the Act, we apply a budget neutrality adjustment to the standardized amount for all hospitals so that this 10-percent cap on relative weight reductions does not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

To calculate this proposed budget neutrality adjustment factor for FY 2027, we used FY 2025 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2026 labor-related share percentages, the proposed FY 2027 relative weights before applying the 10-percent cap, and the FY 2026 pre-reclassified wage data, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously); and
- Aggregate payments using the FY 2026 labor-related share percentages, the proposed FY 2027 relative weights after applying the 10-percent cap, and the FY 2026 pre-reclassified wage data, and applied the same proxy FY 2027 hospital readmissions payment adjustments and proxy FY 2027 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the proposed FY 2027 relative weights, consistent with our proposal in section V.I. of the preamble to this proposed rule and our historical policy, and as discussed in the preceding section, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor before the cap (derived in the first step) to the payment

rates that were used to simulate payments for this comparison of aggregate payments from FY 2026 to FY 2027. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, as we are proposing to apply this budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2026. Please see the table later in this section setting forth each of the proposed FY 2027 budget neutrality factors.

**c. Updated Wage Index—Proposed Budget Neutrality Adjustment**

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index, or budget neutral.

Section 1886(d)(3)(E)(i) of the Act directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the diagnosis related group (DRG) prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36869 through 36873), we finalized a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2025. For FY 2027, we are proposing to continue to use a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2026. Section 1886(d)(3)(E)(ii) of the Act provides that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share results in a higher payment. (We refer the reader to section III.H of the preamble of this proposed rule for a complete discussion about the labor-related share).

As discussed in section III.H of the preamble of this proposed rule, for FY 2027, for all IPPS hospitals (including Puerto Rico hospitals) whose wage

indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2027, we are proposing to apply the wage index to a labor-related share of 66.0 percent of the national standardized amount.

Section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act (among other provisions) had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent.

Section 1886(d)(3)(E)(i) of the Act provides for the collection of data at least every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, to construct an occupational mix adjustment to the wage index. Consistent with current policy, for FY 2027, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.D of the preamble of this proposed rule.

To compute a proposed budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2025 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2027 relative weights and the FY 2026 pre-reclassified wage indexes, applied the FY 2026 labor-related share of 66.0 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proxy hospital readmissions payment adjustment and the proxy hospital VBP payment adjustment (as described previously).

- Aggregate payments using the proposed FY 2027 relative weights and

the proposed FY 2027 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2027 of 66.0 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proxy FY 2027 hospital readmissions payment adjustments and proxy FY 2027 hospital VBP payment adjustments applied previously.

In addition, we applied the proposed MS-DRG reclassification and recalibration budget neutrality adjustment factor before the proposed cap (derived in the first step) and the 10-percent cap on relative weight reductions adjustment factor (derived from the second step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2026 to FY 2027. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the proposed FY 2027 budget neutrality factors.

#### d. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note, in the FY 2024 IPPS/LTCH final rule (88 FR 58971 through 58977), we finalized a policy beginning with FY 2025 to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and only exclude “dual reclass” hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous policy, beginning with FY 2024, we include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of “the wage index for rural areas in the State in which the county

is located” as referred to in section 1886(d)(8)(C)(iii) of the Act.

We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) of the Act shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality adjustment factor for FY 2027, we used FY 2025 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2027 labor-related share percentage, the proposed FY 2027 relative weights, and the proposed FY 2027 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously).

- Aggregate payments using the proposed FY 2027 labor-related share percentage, the proposed FY 2027 relative weights, and the proposed FY 2027 wage data after such reclassifications, and applied the same proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this proposed rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks for FY 2027 and applies the policies explained in section III of the preamble of this proposed rule. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this proposed factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the proposed FY 2027 budget neutrality factors.

The proposed FY 2027 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2026 budget neutrality adjustment factor. We note that the proposed FY 2027 budget neutrality adjustment reflects FY 2027 wage index reclassifications approved

by the MGCRB or the Administrator at the time of development of this proposed rule.

#### e. Proposed Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) are equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index.

In fiscal years in which there are no hospitals in rural Puerto Rico with wage data, similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), we calculate a national rural Puerto Rico wage index. In such years, our calculation of the national rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all urban areas that are contiguous to (share a border with) the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Based on the current labor market area delineations used for the wage index, all Puerto Rico urban areas are contiguous to a rural area. Therefore, the national rural Puerto Rico wage index is calculated based on the average of the proposed FY 2027 wage indexes for the following urban areas: Aguadilla, PR (CBSA 10380); Arecibo, PR (CBSA 11640); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); and San Juan-Bayamon-Caguas, PR (CBSA 41980).

We note, in the FY 2024 IPPS/LTCH final rule (88 FR 58971–77), we finalized a policy beginning with FY 2025 to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations and to only exclude “dual reclass” hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous policy, beginning with FY 2024, we include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of the rural floor.

To calculate the proposed national rural floor budget neutrality adjustment factor, we used FY 2025 discharge data to simulate payments, and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the rural floor.
- National simulated payments with the rural floor.

Based on this comparison, we determined a proposed national rural floor budget neutrality adjustment factor. The proposed national adjustment was applied to the national wage indexes to produce proposed rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the proposed FY 2027 budget neutrality factors.

As further discussed in section III.G.2 of this proposed rule, section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021, amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index (or imputed floor) for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Unlike the imputed floor that was in effect from FY 2005 through FY 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In the past, we budget neutralized the estimated increase in payments each year resulting from the imputed floor that was in effect from FY 2005 through FY 2018. For FY 2022 and subsequent years, in applying the imputed floor required under section 1886(d)(3)(E)(iv) of the Act, we are applying the imputed floor after the application of the rural floor and would apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor. We refer the reader to section III.G.2 of the preamble of this proposed rule for a complete discussion regarding the imputed floor.

#### f. Permanent Cap Policy for Wage Index—Proposed Budget Neutrality Adjustment

As noted previously, in section III.G.6 of the preamble to this proposed rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021) we finalized a policy to apply a 5-percent

cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We also finalized the application of this permanent cap policy in a budget neutral manner through an adjustment to the standardized amount to ensure that estimated aggregate payments under our wage index cap policy for hospitals that will have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent will equal what estimated aggregate payments would have been without the permanent cap policy.

To calculate a wage index cap budget neutrality adjustment factor for FY 2027, we used FY 2025 discharge data to simulate payments and compared the following:

- Aggregate payments without the 5-percent cap using the proposed FY 2027 labor-related share percentages and the proposed FY 2027 relative weights, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously).
- Aggregate payments with the 5-percent cap using the proposed FY 2027 labor-related share percentages and the proposed FY 2027 relative weights, and applied the same proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments applied previously.

#### g. Proposed Continued Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor

In the FY 2025 interim final action with comment period (IFC) (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. For FY 2026 and subsequent fiscal years, consistent with the FY 2025 IFC, after considering the D.C. Circuit's decision in *Bridgeport Hospital v. Becerra*, we discontinued the low wage index hospital policy and the application of the low wage index budget neutrality factor to the standardized amounts.

For FY 2025 and FY 2026, consistent with our past practice to establish temporary transition policies to mitigate short-term instability and payment fluctuations, we established transition policies for hospitals significantly impacted by the discontinuation of the low wage index hospital policy using

our authority under section 1886(d)(5)(I) of the Act. The transitional payment exception for FY 2025 for those hospitals was equal to the additional FY 2025 amount a hospital would have been paid under the IPPS if its FY 2025 wage index were equal to 95 percent of its FY 2024 wage index. The transitional payment exception for FY 2026 was equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024 wage index.<sup>556</sup> For FY 2025, we opted not to budget neutralize the interim transition policy given the timing of the *Bridgeport Hospital v. Becerra* decision. However, for FY 2026, we finalized a payment transition with a budget neutrality adjustment through notice-and-comment rulemaking for hospitals facing significant reductions over two years that would not be sufficiently mitigated by the wage index cap policy at 42 CFR 412.64(h)(7). We refer readers to the FY 2025 IFC (89 FR 80405 through 80421) and to the FY 2026 IPPS/LTCH PPS Final Rule (90 FR 36855 through 36857) for a full discussion of these transitional payment policies.

Some hospitals that previously benefitted from the low wage index hospital policy would continue to experience decreases of approximately 5 percent or more per year from their FY 2024 wage index (with the low wage index hospital policy applied). Therefore, we are proposing to extend the transitional exception to the calculation payments for FY 2027 a for these hospitals in the same manner as we did for the FY 2026 wage index. As noted previously, in section III.G.6 of the preamble to this proposed rule, for FY 2027 we are proposing to use our authority under section 1886(d)(5)(I)(i) of the Act twice. First, we are proposing to adopt a narrow transitional exception to the calculation of FY 2027 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. Second, we are proposing to exercise our authority again to do so in a budget neutral manner. To calculate the proposed transition wage index budget neutrality adjustment factor for FY 2027, we used FY 2025 discharge data to simulate payments and compared the following:

- Aggregate payments without the transition for the discontinuation of the low wage index hospital policy, the 5-percent cap using the proposed FY 2027

<sup>556</sup> 90.25 percent = 95 percent for FY 2025 \* 95 percent for FY 2026. This can also be expressed as .95\*2.

labor-related share percentages, the proposed FY 2027 relative weights, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously).

- Aggregate payments with the proposed transition for the discontinuation of the low wage index hospital policy, the 5-percent cap using

the proposed FY 2027 labor-related share percentages the proposed FY 2027 relative weights, and applied the same proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments applied previously. This proposed FY 2027 budget neutrality adjustment factor was applied to the standardized amount.

We note, Table 2 associated with this proposed rule contains the wage index by provider before and after applying the 5 percent cap and the transition for the discontinuation of the low wage index hospital policy.

The following table is a summary of the proposed FY 2027 budget neutrality factors, as discussed in the previous sections.

| SUMMARY OF PROPOSED FY 2027 BUDGET NEUTRALITY FACTORS                                                       |          |
|-------------------------------------------------------------------------------------------------------------|----------|
| MS-DRG Reclassification and Recalibration Budget Neutrality Factor                                          | 0.998687 |
| Cap Policy MS-DRG Weights Budget Neutrality Factor                                                          | 0.999753 |
| Wage Index Budget Neutrality Factor                                                                         | 1.000296 |
| Reclassification Budget Neutrality Factor                                                                   | 0.972154 |
| *Rural Floor Budget Neutrality Factor                                                                       | 0.985465 |
| Cap Policy Wage Index Budget Neutrality Factor                                                              | 0.991972 |
| Continued Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor | 0.999782 |

\*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

#### i. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for “outlier” cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, any new technology add-on payments, and the “outlier threshold” or “fixed-loss” amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, any new technology add-on payments, and the outlier threshold as the outlier “fixed-loss cost threshold.” To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital’s CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2027 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost

factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total projected operating outlier payments by the total projected operating DRG payments plus projected operating outlier payments. As discussed in the next section, for FY 2027, we are incorporating an estimate of the impact of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated total of outlier payments as a proportion of total DRG payments. More information on outlier payments may be found on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html>.

(1) Methodology To Incorporate a Proposed Estimate of the Impact of Outlier Reconciliation in the FY 2027 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at

cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. Instructions for outlier reconciliation are in section 20.1.2.5 of chapter 3 of the Claims Processing Manual (available at <https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104c03.pdf>). The original instructions issued in July 2003<sup>557</sup> instruct MACs to identify for CMS any instances where: (1) a hospital’s actual operating CCR for the cost reporting period fluctuates plus or minus 10 percentage points or more compared to the interim operating CCR used to calculate outlier payments when a bill is processed; and (2) the total operating and capital outlier payments for the hospital exceeded \$500,000 for that cost reporting period. Cost reports that meet these criteria will have the hospital’s outlier payments reconciled at the time of cost report final settlement if approved by the CMS Central Office. For the remainder of this discussion, we refer to these criteria as the original criteria for outlier reconciliation (or the original criteria).

On March 28, 2024, we issued Change Request (CR) 13566, which is available at <https://www.cms.gov/medicare/regulations-guidance/transmittals/2024-transmittals/r12594cp>. CR 13566

<sup>557</sup> Change Request 2785 (Transmittal A–03–058; July 3, 2003) found at <https://www.cms.gov/regulations-and-guidance/transmittals/downloads/a03058.pdf>.

provided additional instructions to MACs for cost reports beginning on or after October 1, 2024 that expand the criteria for identifying cost reports MACs are to refer to CMS for approval of outlier reconciliation. On September 22, 2025, we issued Change Request (CR) 14233, which is available at <https://www.cms.gov/medicare/regulations-guidance/transmittals/2025-transmittals/r13428cp>, which delayed the implementation of CR 13566 to cost reports beginning on or after October 1, 2025. As discussed in the FY 2025 IPPS/LTCH final rule, we anticipate that MACs will identify more cost reports to refer to CMS for outlier reconciliation approval. Specifically, CR 14233 instructs for cost reports beginning on or after October 1, 2025, MACs shall identify for CMS any instances where: (1) the actual operating CCR is found to be plus or minus 20 percent or more from the operating CCR used during that time period to make outlier payments, and (2) the total operating and capital outlier payments for the hospital exceeded \$500,000 for that cost reporting period. For the remainder of this discussion, we refer to these criteria as the new criteria for outlier reconciliation (or the new criteria). These new criteria for identifying hospital cost reports that MACs identify for outlier reconciliation approval are in addition to the original criteria for reconciliation described previously. That is, under the new criteria, MACs identify hospitals for outlier reconciliation approval that would not have met the original criteria. In addition, CR 14233 instructs that for cost reporting periods that begin on or after October 1, 2025, a hospital in its first cost reporting period will be referred for reconciliation of outlier payments at the time of cost report final settlement. As such, new hospitals will be referred for outlier reconciliation approval regardless of the change to the operating CCR and no matter the amount of outlier payments during the cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual for complete instructions regarding outlier reconciliation, including the update to the outlier reconciliation criteria provided in CR 14233. (Refer to the FY 2025 IPPS/LTCH PS final rule for additional information (89 FR 69950).)

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42635), we finalized a methodology to incorporate

outlier reconciliation in the FY 2020 outlier fixed loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the methodology addresses stakeholder's concerns on the impact of outlier reconciliation on the modeling of the outlier threshold. (For a detailed discussion of additional background regarding outlier reconciliation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule.)

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69949 through 69955), we finalized changes to our methodology to incorporate an estimate of outlier reconciliation in the FY 2025 outlier fixed loss cost threshold to reflect the estimated reconciled outlier payments under the new criteria (described previously). (We note, when we finalized these changes to the methodology beginning with FY 2025, CR 13566 was in place making the new criteria in effect for cost reports beginning on or after October 1, 2024.) In that final rule, we provided step by step details under our methodology to incorporate a projection of outlier payment reconciliations for the FY 2025 outlier threshold calculation. We refer the reader to the FY 2025 IPPS/LTCH final rule for complete details (89 FR 69950 through 69955).

#### (a) Incorporating a Proposed Projection of Outlier Reconciliations for the FY 2027 Outlier Threshold Calculation

Under our methodology for incorporating a projection of outlier reconciliation for the outlier threshold calculation, for each year, we typically advance the historical data used by 1 year, using cost report data that is on a 6-year lag, which is typically the most recent and complete available data to project the estimate of outlier reconciliation. Accordingly, for FY 2025 we used FY 2019 cost report data. Because at that time, the new criteria were not effective until FY 2025 cost reports, to estimate outlier reconciliation dollars under the new criteria, we applied the new criteria to FY 2019 cost reports as if they had been in place at the time of final cost report settlement. (As noted previously, when

we finalized these changes to the methodology beginning with FY 2025, CR 13566 was in place making the new criteria in effect for cost reports beginning on or after October 1, 2024.) In FY 2026, we evaluated the FY 2020 cost report data under our methodology as established in FY 2020 and modified in the FY 2025 IPPS/LTCH PPS final rule. As discussed in the FY 2026 IPPS/LTCH PPS final rule, based on our evaluation of the data, for purposes of incorporating an estimate of outlier reconciliation in the outlier fixed-loss cost threshold calculation for FY 2026, we held the data constant and used the percentage of total operating outlier reconciliation dollars to total Federal operating payments from the FY 2025 IPPS/LTCH PPS final rule, which was based on FY 2019 cost reports and PSF data.

For FY 2027, we evaluated the use of the FY 2021 cost report data under our methodology as established in FY 2020 and modified in the FY 2025 IPPS/LTCH PPS final rule, to incorporate a projection of operating outlier reconciliations for the FY 2027 outlier threshold calculation (that is, the FY 2020 methodology as modified in FY 2025 to reflect additional cost reports that would be identified for outlier reconciliation approval under the new criteria in CR 14233). Specifically, for FY 2027 we evaluated using the same steps finalized in the FY 2025 IPPS/LTCH PPS final rule.

Specifically, we calculated a projection of outlier reconciliation using cost report data from FY 2021 hospital cost reports in the December 2025 HCRIS extract that were reconciled using the original criteria for referral for outlier reconciliation approval. In addition, in calculating this estimate, we used data from the Provider Specific File (PSF) and the cost report data to identify the FY 2021 cost reports that would have met the new criteria if those criteria had been in effect. This allows us to account for the additional hospital cost reports that would be referred for outlier reconciliation approval as a result of the new criteria under our methodology. For purposes of this estimate, we used the latest quarterly PSF update (December 2025 for the proposed rule).

As explained previously, our 5-step methodology to incorporate a projection of outlier payment reconciliations for the outlier threshold calculation is described in detail in the FY 2025 IPPS/LTCH final rule (see 89 FR 69950 through 69952). The 5 steps can be summarized as follows:

*Step 1:* Identify hospital cost reports that meet the original criteria (Step 1a) or the new criteria (Step 1b).

*Step 2:* Determine the aggregate amount of operating outlier reconciliation dollars (under both the original criteria (Step 2a) and the new criteria (Steps 2b)).

*Step 3:* Calculate the aggregate amount of total Federal operating payments across all applicable hospitals using the cost report data.

*Step 4:* Determine the percentage of total operating outlier reconciliation dollars to total Federal operating payments for the cost report data year.

*Step 5:* Adjust the outlier target using the percentage from Step 4.

With regard to incorporating outlier reconciliation in the FY 2027 outlier fixed-loss cost threshold, we evaluated the use of the most recent available data (as described previously) using the 5-step methodology as set forth in the FY 2025 IPPS/LTCH PPS final rule. As we explain in greater detail in the discussion that follows, similar to FY 2026, we found that using the most recent available data under our 5-step methodology appears to produce anomalous results that may not provide an appropriate estimate and predictor of outlier reconciliation for the upcoming fiscal year. (We note, for the hospitals identified in Step 1b (hospitals that would be referred for outlier reconciliation under the new criteria), for this proposed rule we posted a public use file that includes the operating CCR calculated from the FY 2021 cost report in the most recent publicly available quarterly HCRIS extract (the December 2025 HCRIS for the proposed rule), the weighted operating CCR used for claim payment during the FY 2021 cost reporting period from the latest quarterly PSF update (December 2025 for the proposed rule), and the supplemental data from the MACs and operating outlier payment reported on the FY 2021 cost report.)

Step 4 of the methodology divides the aggregate amount from Step 2<sup>558</sup> (operating outlier reconciliation dollars under both the original criteria and the new criteria or total reconciled dollars) by the amount from Step 3<sup>559</sup> (total

Federal operating payments across all applicable hospitals using the cost report data) and multiplies the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments (89 FR 69952). As discussed in previous proposed and final rules, when the percentage of total operating outlier reconciliation dollars to total Federal operating payments in Step 4 rounds to a negative value, the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. When the percentage of total operating outlier reconciliation dollars to total Federal operating payments in Step 4 rounds to a positive value, the effect is an increase to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars.

Using the most recent available data for this proposed rule (as described previously), the ratio calculated under Step 4 of the methodology would be 0.000000 percent ( $(\$457,535 / \$77,326,439,126) \times 100$ ), which, when rounded to the second digit, is +0.0 percent. Under Step 5 of the methodology, this percentage amount would be used to adjust the outlier target for FY 2027. This would mean that for FY 2027, we would incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.1 percent [5.1 percent—(0.0 percent)]. This 0.0 percentage is being driven by the numerator in Step 4 (that is, the total reconciled dollars or the aggregate operating outlier reconciliation dollars under both the original criteria and the new criteria).

Typically, the total reconciled dollars in Step 2 (the numerator of Step 4) is a negative amount reflecting that overall, providers would owe the Medicare program money at the time of outlier reconciliation, which then produces a negative percentage of operating outlier reconciliation dollars to total Federal operating payments in Step 4. Using the most recent available data (described previously), the total reconciled dollars in Step 2 (the numerator of Step 4) which is the aggregate operating outlier reconciliation dollars under both the original criteria and the new criteria, is resulting in a small amount owed by CMS to providers (\$457,535). When Step 2 is divided by the aggregate amount of total Federal operating

payments across all applicable hospitals using the cost report data in Step 3 (\$77,326,439,126; the denominator in Step 4), this results in no adjustment to the threshold (0.0 percent).

As mentioned previously, since FY 2020 we have incorporated outlier reconciliation into the outlier fixed loss cost threshold calculation. For the outlier fixed loss cost threshold calculation for FYs 2020 through 2025, the percentage of operating outlier reconciliation dollars to total Federal operating payments from Step 4 has resulted in a negative value (having the effect of a decrease to the outlier threshold). Similar to the evaluation of FY 2020 cost report data for FY 2026, using the FY 2021 cost report data and PSF values described previously under our methodology would result in a percentage of operating outlier reconciliation dollars to total Federal operating payments that is inconsistent with the prior historical data. Similar to the evaluation of the FY 2020 cost report data for FY 2026, compared to the historical data used to calculate the estimate of outlier reconciliation for FYs 2020–2025, we believe 0.0 percent may be an anomaly and may not be an accurate predictor of outlier reconciliations for FY 2027 to use as an estimate of outlier reconciliation dollars for incorporating the effect of outlier reconciliation in the FY 2027 outlier fixed-loss cost threshold. Therefore, rather than use the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 based on the latest available data (as described previously), for purposes of incorporating an estimate of outlier reconciliation into the outlier fixed-loss cost threshold calculation for FY 2027, we are proposing to hold the data constant and to use the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data. As discussed in that final rule (89 FR 69952), the ratio was a negative 0.041994 percent ( $(-\$36,439,127 / \$86,772,005,692) \times 100$ ), which, when rounded to the second digit, is –0.04 percent. Given the anomaly in the most recent available data described earlier, we believe that this is the best available data to estimate and predict outlier reconciliations for FY 2027 to use to incorporate the effect of outlier reconciliation in the FY 2027 outlier fixed-loss cost threshold. This percentage amount would then be used to adjust the proposed outlier target for FY 2027 as determined in Step 5. (For

<sup>558</sup> Step 2, the numerator of step 4, is the aggregate amount of operating outlier reconciliation dollars under both the original criteria and the new criteria which is the sum of the amounts from Steps 2a and 2b. (89 FR 69951 through 69952).

<sup>559</sup> Step 3, the denominator of step 4, is the aggregate amount of total Federal operating payments across all applicable hospitals using the cost report data (i.e., FY 2021 cost reports for FY 2027). The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04),

outlier payments (Worksheet E, Part A, Lines 2.02, 2.03, and 2.04), and the outlier reconciliation amounts from Steps 2a and 2b. (89 FR 69952).



complete details on the calculation, refer to the FY 2025 IPPS/LTCH final rule (89 FR 69950 through 69952).)

Under Step 5 of our methodology, because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we are proposing to target 5.1 percent minus the percentage determined under Step 4 in determining the outlier threshold. Consistent with the FY 2025 IPPS/LTCH PPS final rule, to incorporate a projection of outlier reconciliation dollars, we are proposing to target an outlier threshold at an amount higher than 5.1 percent for outlier payments for FY 2027. Therefore, for FY 2027, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent – (–0.04 percent)]. As explained earlier, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent, the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of this Addendum, we provide the FY 2027 proposed outlier threshold as calculated for this proposed rule both with and without including this percentage estimate of operating outlier reconciliation.

Consistent with the approach taken in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19593), we would continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. Therefore, the proposed operating outlier offset to the standardized amount is 0.949 (1 – 0.051).

We note, for the FY 2027 final rule, consistent with our historical practice, we plan to evaluate the updated data available at the time of the development of that final rule (such as the March 2026 HCRIS extract of the FY 2021 cost report). We would evaluate the use of that updated data in the methodology to assess whether that data still shows an anomaly such that it would not be appropriate to use in calculating the projection of outlier reconciliation dollars for FY 2027 and, depending on the results of this evaluation, may consider use of that data for purposes of projecting an estimate of outlier reconciliation dollars and incorporating that estimate into the modeling for the fixed loss cost outlier threshold for FY 2027. We are inviting public comment on our proposed methodology for

projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed loss cost outlier threshold for FY 2027.

(b) Proposed Adjustment To Account for Capital Outlier Reconciliation Payments in the Projected Proportion of Capital IPPS Payments Paid as Outliers in Determining the FY 2027 Capital Federal Rate

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we are proposing to reduce the FY 2027 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement would be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments.

Under our methodology for incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers in determining the FY 2027 capital Federal rate, each year, we typically advance the historical data used by 1 year and use cost report data that is on a six year lag, which is typically the most recent and complete available data to project the estimate of outlier reconciliation. Accordingly, for FY 2025 we used FY 2019 cost report data. Because at that time, the new criteria were not effective until FY 2025 cost reports, to estimate outlier reconciliation dollars under the new criteria, we applied the new criteria to FY 2019 cost reports as if they had been in place at the time of final cost report settlement. (As noted previously, when we finalized these methodology changes beginning with FY 2025, CR 13566 was in place making the new criteria in effect for cost reports beginning on or after October 1, 2024.) In FY 2026, we evaluated the FY 2020 cost report data under our methodology as established in FY 2020 and modified in the FY 2025 IPPS/LTCH PPS final rule. As discussed in the FY 2026 IPPS/LTCH PPS final

rule, based on our evaluation of the data, for purposes of incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers in determining the FY 2026 capital Federal rate, we held the data constant and used the percentage of total capital outlier reconciliation dollars to total capital Federal payments from the FY 2025 IPPS/LTCH PPS final rule, which was based on FY 2019 cost reports and PSF data.

For FY 2027, we evaluated the use of the FY 2021 cost report data under the methodology we used for FY 2025 to incorporate an adjustment to the FY 2027 capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers (that is, the FY 2020 methodology as modified in FY 2025 to reflect additional cost reports that would be identified for reconciliation under the new criteria in CR 14233). Specifically, we calculated an estimate of outlier reconciliation using cost report data from FY 2021 hospital cost reports in the December 2025 HCRIS extract that were reconciled using the original criteria for referral for outlier reconciliation. Similarly, in calculating this estimate, we used data from the Provider Specific File (PSF) and the cost report data to identify the FY 2021 cost reports that would have met the new criteria if those criteria had been in effect. This allowed us to account for the additional hospital cost reports that would be referred for outlier reconciliation approval as a result of the new criteria under our methodology. For purposes of the estimate, we used the latest quarterly PSF update (December 2025) for the proposed rule.

As previously explained, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 699540 through 69955), we finalized changes to our methodology to incorporate an estimate of outlier reconciliation in the FY 2025 outlier fixed loss cost threshold to reflect the estimated reconciled outlier payments under the new criteria in CR 13566 (described previously). In that final rule, we provided step by step details under our methodology to incorporate a projection of outlier payment reconciliations for the FY 2025 outlier threshold calculation. (For complete details on our 5-step methodology to incorporate an adjustment to the capital outlier adjustment factor, we refer readers to the FY 2025 IPPS/LTCH final rule (89 FR 69953 through 69955).) The 5 steps can be summarized as follows:

*Step 1:* Identify hospital cost reports that meet the original criteria (Step 1a) or the new criteria (Step 1b).



*Step 2:* Determine the aggregate amount of capital outlier reconciliation dollars (under both the original criteria (Step 2a) and the new criteria (Steps 2b)).

*Step 3:* Calculate the aggregate amount of total capital Federal payments across all applicable hospitals using the cost report data.

*Step 4:* Determine the percentage of total capital outlier reconciliation dollars to total capital Federal payments for the cost report data year.

*Step 5:* Adjust the capital outlier adjustment factor using the percentage from Step 4.

Under this methodology, because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, in Step 5 the estimate of capital outlier payments are determined by adding the percentage determined in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a “target” percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.)

As discussed in previous proposed and final rules, when the aggregate capital outlier reconciliation dollars in Step 2 is negative, the estimate of capital outlier payments under our methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared

outlier threshold. Under Step 5 this would be a relatively smaller outlier budget neutrality adjustment factor which would have the effect of an increase to the capital Federal rate. When the aggregate capital outlier reconciliation dollars from Step 2 are positive, the estimate of capital outlier payments under our methodology would be higher than the percentage of capital outlier payments otherwise determined using the shared outlier threshold. Under Step 5 this would be a relatively larger outlier budget neutrality adjustment factor which would have the effect of a decrease to the capital Federal rate.

With regard to incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers, we evaluated the use of the most recent available data (as described previously) using the 5-step methodology as set forth in the FY 2025 IPPS/LTCH PPS final rule. (We note, for the hospitals identified in Step 1b (hospitals that would be referred for outlier reconciliation approval under the new criteria), for this proposed rule we posted a public use file that includes the capital CCR calculated from the FY 2021 cost report in the most recent publicly available quarterly HCRIS extract (the December 2025 HCRIS for the proposed rule), the weighted capital CCR used for claim payment during the FY 2021 cost reporting period from the latest quarterly PSF update (December 2025 for the proposed rule), and the supplemental data from the MACs and capital outlier payment reported on the FY 2021 cost report.)

Step 4 of the methodology divides the aggregate amount from Step 2<sup>4</sup> (capital outlier reconciliation dollars under both the original criteria and the new criteria or total reconciled dollars) by the amount from Step 3<sup>5</sup> (total Federal capital payments across all applicable hospitals using the cost report data) and multiplies the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments (89 FR

<sup>4</sup> Step 2, the numerator of step 4, is the aggregate amount of capital outlier reconciliation dollars under both the original criteria and the new criteria which is the sum of the amounts from Steps 2a and 2b. (89 FR 69954 through 69955).

<sup>5</sup> Step 3, the denominator of step 4, is the aggregate amount of total capital Federal payments across all applicable hospitals using the cost report data. The total capital Federal payments consist of the capital DRG payments, capital outlier payments, capital indirect medical education (IME) Payments, capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation amounts from Steps 2a and 2b. (89 FR 69955).

69955). Under the methodology, in Step 5 this amount is added to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold (as explained previously).

For this proposed rule, the estimated percentage of FY 2027 capital outlier payments otherwise determined using the shared outlier threshold is 3.60 percent (estimated capital outlier payments of \$264,774,667 divided by (estimated capital outlier payments of \$264,774,667 plus the estimated total capital Federal payment of \$7,080,040,076)). Using the most recent available data (described previously), the total in Step 2 is \$4,597,730, which is a negative amount. The percentage calculated in Step 4 was a negative 0.065876 percent  $((\$4,597,730 / \$6,979,384,161) \times 100)$ , which, when rounded to the second digit, is  $-0.07$  percent. Under Step 5 of the methodology, this percentage amount would be used to adjust the estimate of capital outlier payments for FY 2027. This would mean that for this FY 2027 proposed rule we would decrease the estimated percentage of FY 2027 aggregate capital outlier payments by 0.07 percent. This negative 0.07 percentage point is being driven by the numerator in Step 4 (that is, the total reconciled dollars or the aggregate capital outlier reconciliation dollars under both the original criteria and the new criteria).

The total reconciled dollars in Step 2 (the numerator of Step 4) is a negative amount reflecting that overall, providers would owe the Medicare program money at the time of outlier reconciliation, which then produces a negative percentage of capital outlier reconciliation dollars to total Federal capital payments in Step 4. This is consistent with the trends in the historical data.

However, as discussed earlier, using the FY 2021 cost report data and PSF values under our methodology for incorporating a projection of operating outlier reconciliations for the outlier threshold calculation would result in a percentage of operating outlier reconciliation dollars to total Federal operating payments that is inconsistent with the historical data. As previously discussed, compared to the historical data used to calculate the estimate of outlier reconciliation for FYs 2020–2025, we believe that 0.0 percent may be an anomaly and may not be an accurate predictor of outlier reconciliations for FY 2027 to use as an estimate of outlier reconciliation dollars for incorporating the effect of outlier reconciliation in the FY 2027 outlier fixed-loss cost

threshold. Therefore, for purposes of incorporating an estimate of outlier reconciliation into the outlier fixed-loss cost threshold calculation for FY 2027, we are proposing to hold the data constant and to use the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data rather than use the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 based on the latest available data. For this reason, to ensure the use of consistent data for incorporating a projection of operating and capital outlier reconciliations, for purposes of incorporating an adjustment to the capital standard Federal rate for FY 2027, we are proposing to also hold the data constant and to use the percentage of total capital outlier reconciliation dollars to total capital Federal payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data rather than use the percentage of total capital outlier reconciliation dollars to total capital Federal payments from Step 4 based on the latest available data. We believe aligning the projection of operating and capital outlier reconciliations based on data from the same period (2019 cost reports) is a consistent and methodologically sound approach for ensuring comparability across calculations and minimizes possible distortions that could result from using data from different reporting periods.

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69955), based on FY 2019 cost reports and PSF data, the ratio was a negative 0.028042 percent ( $(-\$2,181,440/\$7,779,306,800) \times 100$ ), which, when rounded to the second digit, is -0.03 percent. Accordingly, for this proposed rule, taking into account projected capital outlier reconciliation under our methodology would decrease the estimated percentage of FY 2027 aggregate capital outlier payments by 0.03 percent. This percentage amount would be used to adjust the proposed estimated percentage of FY 2027 aggregate capital outlier payments under Step 5 of the methodology. (For complete details on the calculation, refer to the FY 2025 IPPS/LTCH final rule (89 FR 69953 through 69955).)

As discussed in section III.A.2. of this Addendum, we are incorporating the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the proposed capital Federal rate based on

the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2027.

We note, for the FY 2027 final rule, consistent with our historical practice, we plan to evaluate the updated data available at the time of the development of that final rule (such as the March 2026 HCRIS extract of the FY 2021 cost report). We would evaluate the use of that updated data in the methodology to assess whether that data still shows an anomaly such that it would not be appropriate to use in calculating the projection of outlier reconciliation dollars for FY 2027 and, depending on the results of this evaluation, may consider use of that data for purposes of projecting an estimate of outlier reconciliation dollars and incorporating an adjustment to the FY 2027 capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers. We are inviting public comment on our proposed methodology for incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers in determining the FY 2027 capital Federal rate.

#### (2) Proposed FY 2027 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the proposed FY 2027 outlier threshold, we simulated payments by applying proposed FY 2027 payment rates and policies using cases from the FY 2025 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the Provider-Specific File (PSF) while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the proposed FY 2027 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2025 to FY 2027. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we are using the following methodology to calculate the charge inflation factor for FY 2027:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf>); include CAHs and REHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals that have a “V” in the fifth position of their provider number or a “E” or “F” in the sixth position.

- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate of change in charges per case. We note this is consistent with the methodology used since FY 2014.

- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

- In order to ensure that we capture only FFS claims, we included claims with a “Claim Type” of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

- In order to further ensure that we capture only FFS claims, we excluded claims with a “GHOPAID” indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of “3” for blood clotting with a revenue code of “0636” from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS. As noted previously, we are proposing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule,

payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).

- Because this payment simulation uses the proposed FY 2027 relative weights, consistent with our proposal discussed in section IV.I. of the preamble to this proposed rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years since we typically use claims data for the fiscal year that is 2 years prior to the upcoming fiscal year.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change.

For the same reasons discussed in that rulemaking, for FY 2027, we are proposing to use the same methodology as FY 2020 to determine the charge inflation factor. That is, for FY 2027, we are proposing to use the MedPAR files for the two most recent available Federal fiscal year time periods to calculate the charge inflation factor, as we did for FY 2020. Specifically, for this proposed rule we used the December 2024 MedPAR file of FY 2024 (October 1, 2023, to September 30, 2024) charge data (released for the FY 2026 IPPS/LTCH PPS proposed rule) and the December 2025 MedPAR file of FY 2025 (October 1, 2024, to September 30, 2025) charge data (released for this FY 2027 IPPS/LTCH PPS proposed rule) to compute the proposed charge inflation factor. We are proposing that for the FY 2027 final rule, we would use more recently updated data, that is the MedPAR files from March 2025 for the FY 2024 time period and March 2026 for the FY 2025 time period.

For FY 2027, under this proposed methodology, to compute the 1-year

average annual rate-of-change in charges per case, we compared the average covered charge per case of \$90,776.90 (\$623,467,062,919/6,868,125) from October 1, 2023, through September 30, 2024, to the average covered charge per case of \$97,412.36 (\$677,169,023,175/6,951,572) from October 1, 2024, through September 30, 2025. This rate-of-change was 7.310 percent (1.07310) or 15.154 percent (1.15154) over 2 years. The billed charges are obtained from the claims from the MedPAR file and inflated by the inflation factor specified previously.

As we have done in the past, in this FY 2027 IPPS/LTCH PPS proposed rule, we are proposing to establish the FY 2027 outlier threshold using hospital CCRs from the December 2025 update to the Provider-Specific File (PSF), the most recent available data at the time of the development of the proposed rule. We are proposing to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2027, we are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section). We are also proposing that, if more recent data become available, we would use that data to calculate the final FY 2027 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we have done in the past, we are proposing to adjust the CCRs from the December 2025 update of the PSF by comparing the percentage change in the national average case weighted operating CCR and capital CCR from the December 2024 update of

the PSF to the national average case weighted operating CCR and capital CCR from the December 2025 update of the PSF. We note that we used total transfer-adjusted cases from FY 2025 to determine the national average case weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology, for this proposed rule, we calculated a December 2024 operating national average case-weighted CCR of 0.24059 and a December 2025 operating national average case-weighted CCR of 0.235176. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2024 operating national average case-weighted CCR from the December 2025 operating national average case-weighted CCR and then dividing the result by the December 2024 national operating average case-weighted CCR. This resulted in a proposed one-year national operating CCR adjustment factor of 0.977497.

We used this same proposed methodology to adjust the capital CCRs. Specifically, we calculated a December 2024 capital national average case-weighted CCR of 0.01644 and a December 2025 capital national average case-weighted CCR of 0.015639. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2024 capital national average case-weighted CCR from the December 2025 capital national average case-weighted CCR and then dividing the result by the December 2024 capital national average case-weighted CCR. This resulted in a proposed one-year national capital CCR adjustment factor of 0.951277.

For purposes of estimating the proposed outlier threshold for FY 2027, we used a wage index that reflects the policies discussed in the proposed rule. This includes the following:

- The proposed rural and imputed floor adjustments.
- The proposed State frontier floor adjustments in accordance with section 10324(a) of the Affordable Care Act, Public Law 111–148.

- The proposed out-migration adjustment as added by section 505 of Public Law 108–173.

- Our policy (described in section III.F.5 of the preamble of this proposed rule) to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline.

- The proposed continuation of the transition for the discontinuation of the low wage index hospital policy (as described in section III.F.6 of the preamble of this proposed rule).

If we did not take the aforementioned into account, our estimate of total FY 2027 payments would be too low, and, as a result, the proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation).

As described in sections V.K. and V.L., respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the estimated hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of

the Act such that it would be reasonable to include the payment in the outlier determination under section

1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2027, we are proposing to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally.

Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2027, we are proposing to include estimated FY 2027 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

In addition, consistent with the methodology finalized in the FY 2023 final rule, we are proposing to include the estimated supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals in the computation of the FY 2027 proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are

proposing to incorporate an estimate of FY 2027 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for the FY 2027 proposed rule, we are proposing to hold the data constant and to use the FY 2025 final rule percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data. As discussed in the FY 2025 IPPS/LTCH PPS final rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) was a negative 0.041994 percent, which, when rounded to the second digit, is -0.04 percent. Therefore, for FY 2027, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent - (-0.04 percent)]. Under this proposed approach, we determined a proposed threshold of \$51,704 and calculated total outlier payments of \$4,642,138,720 total operating Federal payments of \$90,312,360,835. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.14 percent target, which reflected our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We note that, if calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the proposed threshold would be \$52,096. We are proposing an outlier fixed-loss cost threshold for FY 2027 equal to the prospective payment rate for the MS-DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus \$51,704.

### (3) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for

FY 2027 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) would result in outlier payments that would equal 5.1 percent of operating DRG payments and we estimate that capital outlier payments would equal 3.57 percent of capital payments based

on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we are proposing to reduce the FY 2027 standardized

amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the FY 2027 outlier threshold are as follows:

|                 | <b>Operating Standardized Amounts</b> | <b>Capital Federal Rate*</b> |
|-----------------|---------------------------------------|------------------------------|
| <b>National</b> | <b>0.949</b>                          | <b>0.964231</b>              |

\*The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2027 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III.A.2 in this Addendum.

We are proposing to apply the outlier adjustment factors to the FY 2027 payment rates after removing the effects of the FY 2026 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.278 or capital CCRs greater than 0.13 or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2026, and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed comparable statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would be used during FY 2027 when

hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

#### (4) FY 2025 Outlier Payments

Our current estimate, using available FY 2025 claims data, is that actual outlier payments for FY 2025 were approximately 4.86 percent of actual total MS-DRG payments. Therefore, the data indicate that, for FY 2025, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2025.

Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2025 are equal to 5.1 percent of total MS-DRG payments. As explained in the FY 2003 Outlier final rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS-DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS-DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2026 period would not be available until after September 30, 2026, we are unable to provide an estimate of actual outlier payments for FY 2026 based on FY 2026

claims data in this proposed rule. We will provide an estimate of actual FY 2026 outlier payments in the FY 2028 IPPS/LTCH PPS proposed rule.

#### 5. Proposed FY 2027 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2027. The proposed standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 66.0 percent, and the labor-related share applied to the standardized amounts in

Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we would apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000. In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2027.

The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2027 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related

share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2026 national standardized amounts to the proposed FY 2027 national standardized amounts. The second through fifth columns display the changes from the FY 2026 standardized amounts for each proposed applicable FY 2027 standardized amount. The first row of the table shows the updated (through FY 2026) average standardized amount after restoring the FY 2026 offsets for outlier payments, geographic reclassification, rural demonstration, and wage index cap policy budget neutrality. The MS–DRG reclassification and recalibration wage index, and stem cell acquisition budget neutrality factors are cumulative (that is, we have not restored the offsets). Accordingly, those FY 2026 adjustment factors have not been removed from the base rate in the following table.

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### CHANGES FROM FY 2026 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2027 STANDARDIZED AMOUNTS

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Hospital Submitted Quality Data and is a Meaningful EHR User                                                                                                                                                                          | Hospital Submitted Quality Data and is NOT a Meaningful EHR User                                                                                                                                                                      | Hospital Did NOT Submit Quality Data and is a Meaningful EHR User                                                                                                                                                                     | Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User                                                                                                                                                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| FY 2026 Base Rate after removing:<br><AMDPAR>1. FY 2026 Geographic Reclassification Budget Neutrality (0.956835)<br><AMDPAR>2. FY 2026 Operating Outlier Offset (0.949)<br><AMDPAR>3. FY 2026 Cap Policy Wage Index Budget Neutrality Factor (0.999397)<br><AMDPAR>4. Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor (0.999726)<br><AMDPAR>5. FY 2026 Rural Demonstration Budget Neutrality Factor (0.999552) | If Wage Index is Greater Than 1.0000:<br>Labor (66.0%):<br>\$4,914.60<br><br>Nonlabor (34.0%):<br>\$2,531.76<br><br>If Wage Index is less Than or Equal to 1.0000:<br>Labor (62%):<br>\$4,616.74<br><br>Nonlabor (38%):<br>\$2,829.62 | If Wage Index is Greater Than 1.0000:<br>Labor (66.0%):<br>\$4,914.60<br><br>Nonlabor (34.0%):<br>\$2,531.76<br><br>If Wage Index is less Than or Equal to 1.0000:<br>Labor (62%):<br>\$4,616.74<br><br>Nonlabor (38%):<br>\$2,829.62 | If Wage Index is Greater Than 1.0000:<br>Labor (66.0%):<br>\$4,914.60<br><br>Nonlabor (34.0%):<br>\$2,531.76<br><br>If Wage Index is less Than or Equal to 1.0000:<br>Labor (62%):<br>\$4,616.74<br><br>Nonlabor (38%):<br>\$2,829.62 | If Wage Index is Greater Than 1.0000:<br>Labor (66.0%):<br>\$4,914.60<br><br>Nonlabor (34.0%):<br>\$2,531.76<br><br>If Wage Index is less Than or Equal to 1.0000:<br>Labor (62%):<br>\$4,616.74<br><br>Nonlabor (38%):<br>\$2,829.62 |
| Proposed FY 2027 Update Factor                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1.024                                                                                                                                                                                                                                 | 1.0                                                                                                                                                                                                                                   | 1.016                                                                                                                                                                                                                                 | 0.9920                                                                                                                                                                                                                                |
| Proposed FY 2027 MS-DRG Reclassification and Recalibration Budget Neutrality Factor Before Cap                                                                                                                                                                                                                                                                                                                                                                   | 0.998687                                                                                                                                                                                                                              | 0.998687                                                                                                                                                                                                                              | 0.998687                                                                                                                                                                                                                              | 0.998687                                                                                                                                                                                                                              |
| Proposed FY 2027 Cap Policy MS-DRG Weight Budget Neutrality Factor                                                                                                                                                                                                                                                                                                                                                                                               | 0.999753                                                                                                                                                                                                                              | 0.999753                                                                                                                                                                                                                              | 0.999753                                                                                                                                                                                                                              | 0.999753                                                                                                                                                                                                                              |
| Proposed FY 2027 Wage Index Budget Neutrality Factor                                                                                                                                                                                                                                                                                                                                                                                                             | 1.000296                                                                                                                                                                                                                              | 1.000296                                                                                                                                                                                                                              | 1.000296                                                                                                                                                                                                                              | 1.000296                                                                                                                                                                                                                              |
| Proposed FY 2027 Reclassification Budget Neutrality Factor                                                                                                                                                                                                                                                                                                                                                                                                       | 0.972154                                                                                                                                                                                                                              | 0.972154                                                                                                                                                                                                                              | 0.972154                                                                                                                                                                                                                              | 0.972154                                                                                                                                                                                                                              |
| Proposed FY 2027 Cap Policy Wage Index Budget Neutrality Factor                                                                                                                                                                                                                                                                                                                                                                                                  | 0.991972                                                                                                                                                                                                                              | 0.991972                                                                                                                                                                                                                              | 0.991972                                                                                                                                                                                                                              | 0.991972                                                                                                                                                                                                                              |
| Proposed Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor                                                                                                                                                                                                                                                                                                                                                       | 0.999782                                                                                                                                                                                                                              | 0.999782                                                                                                                                                                                                                              | 0.999782                                                                                                                                                                                                                              | 0.999782                                                                                                                                                                                                                              |
| Proposed FY 2027 Operating Outlier Factor                                                                                                                                                                                                                                                                                                                                                                                                                        | 0.949                                                                                                                                                                                                                                 | <AMDPAR>0.949                                                                                                                                                                                                                         | <AMDPAR>0.949                                                                                                                                                                                                                         | <AMDPAR>0.949                                                                                                                                                                                                                         |
| National Standardized Amount for FY 2027 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (66.0/34.0)                                                                                                                                                                                                                                                                                                                                      | Labor: \$4,598.80<br>Nonlabor: \$2,369.07                                                                                                                                                                                             | Labor: \$4,491.02<br>Nonlabor: \$2,313.54                                                                                                                                                                                             | Labor: \$4,562.87<br>Nonlabor: \$2,350.56                                                                                                                                                                                             | Labor: \$4,455.09<br>Nonlabor: \$2,295.04                                                                                                                                                                                             |
| National Standardized Amount for FY 2027 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)                                                                                                                                                                                                                                                                                                                                 | Labor: \$4,320.08<br>Nonlabor: \$2,647.79                                                                                                                                                                                             | Labor: \$4,218.83<br>Nonlabor: \$2,585.73                                                                                                                                                                                             | Labor: \$4,286.33<br>Nonlabor: \$2,627.10                                                                                                                                                                                             | Labor: \$4,185.08<br>Nonlabor: \$2,565.05                                                                                                                                                                                             |

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#### *B. Proposed Adjustments for Area Wage Levels and Cost-of-Living*

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the labor-related and nonlabor-related shares that we are using to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia,

and Puerto Rico for FY 2027. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

#### 1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-

related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2027, as discussed in section IV.B.3. of the preamble of this proposed rule, we are proposing to apply a labor-related share of 66.0 percent for the national

standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the FY 2027 wage index.

## 2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) website at <https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/#url=COLA-Rates> to update this nonlabor portion.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the OPM every 4 years (coinciding with the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and Consumer Price Indices (CPIs) data through 2020. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we utilized these COLA factors for FYs 2022 through 2025 to adjust the nonlabor-related portion of the standardized

amount for hospitals located in Alaska and Hawaii.

In general, under our existing methodology, we update the 2009 OPM COLA factors by a comparison of the growth in the CPIs for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We use the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively, because BLS publishes CPI data for only Urban Alaska and Urban Hawaii. Using the respective CPI commodities index and CPI services index and using the approximate commodities/services shares obtained from the IPPS market basket, we create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. Lastly we exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating the statutorily mandated cap of 25 percent that was applied when determining OPM's COLA factors. (For additional information, refer to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547).)

We previously stated our intention to update the COLA factors at the same time as the update to the labor-related share of the IPPS market basket. In the FY 2026 IPPS/LTCH PPS proposed rule, we proposed to update the labor-related share of the IPPS market basket. We also stated that at that time, we believed it would be appropriate to maintain the current COLA factors for FY 2026 to allow us to consider whether it would be appropriate to incorporate additional data sources or other methodology changes in determining the COLA factors we apply to IPPS payments to account for the unique circumstances of hospitals located in Alaska and Hawaii (90 FR 18437 through '18438). Therefore, we proposed to continue to use the FY 2025 COLA factors to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii for FY 2026. We solicited comments on any possible data sources that could be considered in the development of the COLA factors.

As summarized in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37230), one commenter supported CMS' proposal to maintain the current COLA methodology temporarily while we evaluate alternative approaches. The commenter requested that CMS utilize a more sensitive adjustment to reflect cost variation across Alaska. The commenter

stated that tying Alaska's COLA to a single urban index does not reflect higher costs in more remote areas. The commenter also requested that CMS reconsider the 25-percent cap on the COLAs and engage with providers during the development of the new methodology. After consideration of the public comment we received, we finalized our proposal to continue to use the FY 2025 COLA factors to adjust the nonlabor related portion of the standardized amount for hospitals located in Alaska and Hawaii for FY 2026.

After further consideration, effective for FY 2027, we are proposing to adjust non-labor related costs for hospitals located in Alaska and Hawaii, using the Overseas Cost-of-Living Allowance (OCOLA) data<sup>560</sup> published by the Department of Defense (DOD). These OCOLAs are received by Service members serving outside of the contiguous U.S. (OCONUS) and are designed to offset higher prices of non-housing goods and services in order to equalize purchasing power with members stationed in the contiguous U.S. (CONUS). To calculate the OCOLAs for each OCONUS area, DOD currently uses Living Pattern Survey (LPS) data on purchasing patterns of Service members (e.g. how and where they purchase certain goods and services including whether these are purchased from a commissary, retail store, or online) and price data for approximately 150 goods and services.<sup>561</sup> The DOD compares the OCONUS LPS and price data with similar data obtained in CONUS.

We believe the DOD OCOLAs are an appropriate data source to capture the cost differences of hospital nonlabor-related inputs purchased in the areas of Hawaii and Alaska compared to the continental U.S. The DOD OCOLAs reflect the relative price differences in a basket of non-housing goods and services that would be consistent with many of the nonlabor-related goods and services that hospitals purchase (such as pharmaceuticals, food, and cleaning supplies). In addition, unlike the prior approach that relied on CPI data for urban areas, these relative price differences would account for the additional shipping costs to remote areas. Specifically, the DOD OCOLAs are reflective of the specific areas of

<sup>560</sup> <https://www.travel.dod.mil/Allowances/Overseas-Cost-of-Living-Allowance/>.

<sup>561</sup> Previously, pricing data was collected by Country Allowance Coordinators in each OCONUS location using the Retail Price Schedule. Effective August 2025, the DOD has outsourced the pricing data collection process for OCONUS to a private contractor.



Alaska and Hawaii where hospitals are located.

For the proposed COLA factors for IPPS hospitals located in Alaska and Hawaii for FY 2027, we are proposing to use the OCOLAs published by DOD effective for January 1, 2026. The DOD OCOLAs are available for 26 Alaska locality areas and 6 Hawaii locality areas. Similar to the COLAs used for Alaska and Hawaii for FY 2022 through FY 2026 that are based on the original OPM COLAs, we are proposing to continue to use the four Nonforeign COLA Areas designated by OPM for Alaska and the four Nonforeign COLA Areas designated by OPM for Hawaii as shown in Table II.B.2.

For each of the designated OPM areas for cities in Alaska (City of Anchorage, City of Fairbanks, and City of Juneau), if there is more than one DOD OCOLA within a 50-mile radius of the city, we are proposing to average the DOD OCOLAs within the designated OPM area to calculate the proposed COLA. Specifically, for the COLA factor for the City of Anchorage, we are proposing to average the DOD OCOLAs for the Anchorage and Wasilla locality areas. For the COLA factor for the City of Fairbanks, we are proposing to average

the DOD OCOLAs for the College, Eielson Air Force Base, and Fairbanks locality areas. For the Rest of Alaska COLA, given that there are IPPS hospitals located in two locality areas (Bethel and Kenai), we are proposing to average the DOD OCOLAs for these two locality areas to calculate the proposed COLA.

For Hawaii, the OCOLAs published by DOD are generally consistent with the OPM designated areas. To obtain the COLA factor for the OPM designated area of County of Maui and County of Kalawao, we are proposing to average the DOD OCOLAs for the Maui and Molokai locality areas.

Starting with the FY 2027 payment year, we are proposing to no longer cap the COLA factors at 25 percent. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent<sup>562</sup> and we had exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating this 25-percent cap. Since we are no longer proposing to use the OPM COLA factors, as well as in consideration of the public comment we received, we are exercising our discretionary authority to no longer cap the COLA factors at 1.25. Lastly, for

fiscal years after FY 2027, in order to facilitate stability in payment rates, we are proposing to continue to update the COLA factors at the same time the labor-related share of the IPPS market basket is updated.

Below is a table with the proposed COLA factors for FY 2027, as calculated using this proposed methodology, which indicates that changing the data source and eliminating the 25-percent cap has different impacts by area. We are soliciting comments on this proposed methodology and the use of the DOD OCOLAs, including any comments on how the use of survey data that are specific to Service members, including their access to discounted commissary prices that might be variable by geographic area, may result in differential impacts across the designated areas. We are also requesting comment on any potential modifications to this proposed methodology, including a potential phase-in of the use of these data or a transition period for implementation, which we may consider finalizing in the FY 2027 IPPS/LTCH PPS final rule, after consideration of the comments received.

**TABLE II.B.2: COST-OF-LIVING ADJUSTMENT FACTORS:  
ALASKA AND HAWAII HOSPITALS**

| Areas                                                       | FY 2022 to FY 2026 | Proposed FY 2027 |
|-------------------------------------------------------------|--------------------|------------------|
| <b>Alaska:</b>                                              |                    |                  |
| City of Anchorage and 80-kilometer (50-mile) radius by road | 1.22               | 1.28             |
| City of Fairbanks and 80-kilometer (50-mile) radius by road | 1.22               | 1.32             |
| City of Juneau and 80-kilometer (50-mile) radius by road    | 1.22               | 1.36             |
| Rest of Alaska                                              | 1.24               | 1.44             |
| <b>Hawaii:</b>                                              |                    |                  |
| City and County of Honolulu                                 | 1.25               | 1.20             |
| County of Hawaii                                            | 1.22               | 1.32             |
| County of Kauai                                             | 1.25               | 1.26             |
| County of Maui and County of Kalawao                        | 1.25               | 1.24             |

### *C. Calculation of the Proposed Prospective Payment Rates*

#### **1. General Formula for Calculation of the Prospective Payment Rates for FY 2027**

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2027 equals the Federal rate (which includes uncompensated care payments). As previously discussed,

section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment:

- The Federal national rate (which, as discussed in section V.E. of the

preamble of this proposed rule, includes uncompensated care payments).

- The updated hospital-specific rate based on FY 1982 costs per discharge.
- The updated hospital-specific rate based on FY 1987 costs per discharge.
- The updated hospital-specific rate based on FY 1996 costs per discharge.
- The updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

<sup>562</sup> Section 5941 of title 5, United States Code, and Executive Order 10000 (as amended) authorize

the payment of COLAs in nonforeign areas (<https://www.opm.gov/policy-data-oversight/pay-leave/pay->

[systems/nonforeign-areas/](https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/)). Section 5941 states that the allowance may not exceed 25 percent.

The prospective payment rate for SCHs for FY 2027 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section. The prospective payment rate for MDHs for discharges occurring before January 1, 2027, equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described in this section. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

## 2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

*Note:* The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS-DRG and MS-DRG relative weight (from Table 5) for each claim primarily based on the ICD-10-CM diagnosis and ICD-10-PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

- Federal Payment Rate for Operating Costs =  $\text{MS-DRG Relative Weight} \times [(\text{Labor-Related Applicable Standardized Amount} \times \text{Applicable CBSA Wage Index}) + (\text{Nonlabor-Related Applicable Standardized Amount} \times \text{Cost-of-Living Adjustment})] \times (1 + \text{IME} + (\text{DSH} * 0.25))$
- Federal Payment for Capital Costs =  $\text{MS-DRG Relative Weight} \times \text{Federal Capital Rate} \times \text{Geographic Adjustment Factor} \times (1 + \text{IME} + \text{DSH})$

Step 4—Determine operating and capital costs:

- Operating Costs =  $(\text{Billed Charges} \times \text{Operating CCR})$
- Capital Costs =  $(\text{Billed Charges} \times \text{Capital CCR})$ .

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

- Operating CCR to Total CCR =  $(\text{Operating CCR}) / (\text{Operating CCR} + \text{Capital CCR})$
- Operating Outlier Threshold =  $[\text{Fixed Loss Threshold} \times ((\text{Labor-Related Portion} \times \text{CBSA Wage Index}) + \text{Nonlabor-Related portion})] \times \text{Operating CCR to Total CCR} + \text{Federal Payment with IME, DSH} + \text{Uncompensated Care Payment} + \text{supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals} + \text{New Technology Add-On Payment Amount}$
- Capital CCR to Total CCR =  $(\text{Capital CCR}) / (\text{Operating CCR} + \text{Capital CCR})$
- Capital Outlier Threshold =  $(\text{Fixed Loss Threshold} \times \text{Geographic Adjustment Factor} \times \text{Capital CCR to Total CCR}) + \text{Federal Payment with IME and DSH}$

Step 6—Compute operating and capital outlier payments:

- Marginal Cost Factor = 0.80 or 0.90 (depending on the MS-DRG)
- Operating Outlier Payment =  $(\text{Operating Costs} - \text{Operating Outlier Threshold}) \times \text{Marginal Cost Factor}$
- Capital Outlier Payment =  $(\text{Capital Costs} - \text{Capital Outlier Threshold}) \times \text{Marginal Cost Factor}$

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment and supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments, supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and new technology add-on payments into consideration when calculating outlier payments.

## 3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

### a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. As discussed previously, currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987, or FY 2002 costs per discharge. As noted, under current law, the MDH program is effective for FY 2027 discharges before January 1, 2027.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990, final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

### b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2027

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. As discussed in section V.F. of the preamble of this final rule, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119-75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027.

Accordingly, the proposed applicable percentage increases to the hospital-

specific rates applicable to SCHs and MDHs are the following:

| <b>FY 2026</b>                                                                                         | <b>Hospital Submitted Quality Data and is a Meaningful EHR User</b> | <b>Hospital Submitted Quality Data and is NOT a Meaningful EHR User</b> | <b>Hospital Did NOT Submit Quality Data and is a Meaningful EHR User</b> | <b>Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User</b> |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------|
| Proposed Market Basket Rate-of-Increase                                                                | 3.2                                                                 | 3.2                                                                     | 3.2                                                                      | 3.2                                                                          |
| Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act    | 0                                                                   | 0                                                                       | -0.8                                                                     | -0.8                                                                         |
| Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act | 0                                                                   | -2.4                                                                    | 0                                                                        | -2.4                                                                         |
| Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act                            | -0.8                                                                | -0.8                                                                    | -0.8                                                                     | -0.8                                                                         |
| <b>Proposed Applicable Percentage Increase Applied to Standardized Amount</b>                          | <b>2.4</b>                                                          | <b>0.0</b>                                                              | <b>1.6</b>                                                               | <b>-0.8</b>                                                                  |

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section V.F. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS-DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS-DRG classifications and the recalibration of the MS-DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital specific-rate for an SCH or MDH is adjusted by the MS-DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of this Addendum. In addition, as discussed in section II.E.2.d. of the preamble this proposed rule and previously, we are applying a permanent 10-percent cap on the reduction in a MS-DRG's relative weight in a given fiscal year, as finalized in the FY 2023 IPPS/LTCH PPS final rule. Because SCHs and MDHs use the same MS-DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, consistent with the policy adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900 and 49432 through 49433), the hospital specific-rate for an SCH or MDH would be adjusted by the proposed MS-DRG 10-percent cap budget neutrality factor. The resulting rate is used in determining the payment rate that an SCH or MDH would receive for its discharges beginning on or after October 1, 2026.

### III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital Related Costs for FY 2027

The PPS for acute care hospital inpatient capital related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in- the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we are proposing to use to determine the capital Federal rate for FY 2027, which would be effective for discharges occurring on or after October 1, 2026.

All hospitals (except "new" hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be

adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

#### *A. Determination of the Proposed Federal Hospital Inpatient Capital Related-Prospective Payment Rate Update for FY 2027*

In the discussion that follows, we explain the factors that we are proposing to use to determine the capital Federal rate for FY 2027. In particular, we explain why the proposed FY 2027 capital Federal rate would increase approximately 4.02 percent, compared to the FY 2026 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge would increase approximately 2.3 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

#### *1. Projected Capital Standard Federal Rate Update*

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CPI) and several other policy adjustment factors. Specifically, we adjust the projected CPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous

CIPi forecasts. The proposed update factor for FY 2027 under that framework is 3.1 percent based on a projected 2.8 percent increase in the 2023-based CIPi, a proposed 0.0 percentage point adjustment for intensity, a proposed 0.0 percentage point adjustment for case-mix, a proposed 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a proposed forecast error correction of 0.3 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPi is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2027 CIPi projection in that same section of this Addendum. In this proposed rule, we describe the policy adjustments that we are proposing to apply in the update framework for FY 2027.

The case mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case mix index can change for any of several reasons—

- The average resource use of Medicare patient changes (“real” case mix change);
- Changes in hospital documentation and coding of patient records result in higher weighted-DRG assignments (“coding effects”); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (“reclassification effect”).

We define real case mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004, IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2027, we are projecting a 0.5 percent total increase in the case mix index. We estimated that the real case-mix increase would equal 0.5 percent for FY 2027. The net adjustment for change in case mix is the difference

between the projected real increases in case mix and the projected total increase in case mix. Therefore, the proposed net adjustment for case-mix change in FY 2027 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year’s changes to the DRG classifications and relative weights, to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, for this proposed rule, we have the FY 2025 MedPAR claims data available to evaluate the effects of the FY 2025 DRG reclassification and recalibration as part of our update for FY 2027. We assume for purposes of this adjustment, that the estimate of FY 2025 DRG reclassification and recalibration would result in no change in the case-mix when compared with the case mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2027.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if the difference in the actual increase and projected increase of the capital input price index for any year is greater than 0.25 percentage point in absolute terms. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPi is greater than 0.25 percentage points in absolute terms, it is reflected in the update recommended under this framework. The forecast error in any given year can be derived as the actual CIPi increase less the forecasted CIPi increase. A forecast error of 0.3 percentage point was calculated for the FY 2025 update, for which there are historical data. That is, current

historical data indicate that actual realized price increases (2.9 percent) were 0.3 percentage point higher than the forecasted FY 2025 CIPi increase (2.6 percent) used in calculating the FY 2025 update factor. Since this exceeds the 0.25 percentage point threshold, we are proposing an adjustment for forecast error in the update for FY 2027.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove non cost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the Consumer Price Index for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this proposed rule, we are proposing to continue to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2027 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2027, we are proposing to use an intensity measure that is based on an average of cost per-discharge data from the 5-year period beginning with FY 2020 and extending through FY 2024. Based on these data, we estimated that case-mix constant intensity declined during FYs 2020 through 2024. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that

intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2027. Therefore, we

are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2027.

Earlier, we described the basis of the components we used to develop the

proposed 3.1 percent capital update factor under the capital update framework for FY 2027, as shown in the following table.

### PROPOSED FY 2027 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

|                                                      |      |
|------------------------------------------------------|------|
| Capital Input Price Index*                           | 2.8  |
| Intensity:                                           | 0.0  |
| Case-Mix Adjustment Factors:                         |      |
| Projected Case-Mix Change                            | -0.5 |
| Real Across DRG Change                               | 0.5  |
| Subtotal                                             | 0.0  |
| Effect of FY 2025 Reclassification and Recalibration | 0.0  |
| Forecast Error Correction                            | 0.3  |
| Total Update                                         | 3.1  |

\*The capital input price index represents the 2023-based CIPI.

#### 2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2027, we are proposing to continue to incorporate the impact of estimated operating outlier reconciliation payment amounts into the outlier threshold model. (For more details on our methodology to incorporate an estimate of the impact of operating outlier reconciliation payment amounts into the outlier threshold model, see section II.A.4.i. of this Addendum to this proposed rule.)

For FY 2026, we estimated that outlier payments for capital-related PPS payments would equal 3.84 percent of inpatient capital related-payments based on the capital Federal rate. Based on the threshold discussed in section II.A. of this Addendum, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs would equal 3.61 percent of inpatient capital-related payments based on the capital Federal rate in FY 2027. Using the methodology outlined in section II.A.4.i. of this Addendum, we estimate that taking into account projected capital

outlier reconciliation payments would decrease the estimated percentage of FY 2027 capital outlier payments by 0.03 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 3.58 percent (3.61 percent—0.03 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2027. Accordingly, we are proposing an outlier adjustment factor of 0.9642 in determining the capital Federal rate for FY 2027. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2027 would be lower than the percentage we estimated for FY 2026.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2027 outlier adjustment of 0.9642 is a 0.27 percent change from the FY 2026 outlier adjustment of 0.9616. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2027 is 1.0027 (0.9642/0.9616) so that the proposed outlier adjustment would increase the FY 2027 capital Federal rate by approximately 0.27 percent compared to the FY 2026 outlier adjustment.

#### 3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and

recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.F.6. of the preamble of this proposed rule, in the FY 2025 interim final action with comment period (IFC) (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. The recalculation of the FY 2025 hospital wage index impacted the FY 2025 GAFs. We also removed the budget neutrality adjustment for changes to the GAF for the lowest quartile adjustment from the FY 2025 capital Federal rate. For FY 2026 and subsequent fiscal years, after considering the D.C. Circuit's decision in *Bridgeport Hospital v. Becerra*, we discontinued the low wage index hospital policy.

For FY 2026, we established a payment transition with a budget neutrality adjustment for hospitals significantly impacted by the discontinuation of the low wage index hospital policy. The transitional payment exception for FY 2026 was equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024 wage index. Under that transitional policy, we made a budget neutral equivalent exception under the capital IPPS for FY 2026. We refer readers to the FY 2026 IPPS/LTCH PPS final rule (90 FR 37234 through 37235) for a full discussion on the FY 2026 transitional payment exception under the capital IPPS.

As discussed in III.F.6 of this proposed rule, we recognize that some hospitals that previously benefitted from the low wage index hospital policy would experience decreases of 15 percent or more over the three years from their FY 2024 wage index (with the low wage index hospital policy applied) to their FY 2027 wage index. Therefore, in addition to our 5-percent wage index cap policy at 42 CFR 412.64(h)(7), we are proposing to extend the transitional exception to the calculation of payments for FY 2027 for hospitals significantly impacted by the discontinuation of the low wage index hospital policy in a budget neutral manner. The transitional payment exception will end when the impact of discontinuing the low wage index hospital policy is mitigated and the hospital's wage index decrease is less than 95 percent for each year since 2024 (also expressed as  $0.95 - n$ , with  $n$  being the number of years since FY 2024). Specifically, for FY 2027, for hospitals that benefitted from the low wage index hospital policy in FY 2024 and whose FY 2027 wage index is decreasing by more than 14.2625 percent from the hospital's FY 2024 wage index, we would continue a transitional payment exception for FY 2027 for that hospital that would be equal to the additional FY 2027 amount the hospital would be paid under the IPPS if its FY 2027 wage index were equal to 85.7375 percent of its FY 2024 wage index. Under this proposed policy, we are making a budget neutral equivalent exception under the capital IPPS. In this section, we refer to this proposed policy as the transition for the discontinuation of the low wage index hospital policy.

As referenced previously, beginning in FY 2023, we finalized at 42 CFR 412.64(h)(7) a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY regardless of the circumstances causing the decline. That is, under this policy, a hospital's wage index value would not be less than 95 percent of its prior year value (87 FR 49018 through 49021). In this section, we refer to our policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year as the 5-percent cap on wage index decreases policy. We note that the proposed transitional payment exception for FY 2027 discussed previously would be applied after the application of the 5-percent cap on wage index decreases policy.

For this proposed rule, we propose to use a 2-step methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those

proposed wage index changes on the GAFs. In the first step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy, consistent with our historical GAF budget neutrality factor methodology. In the second step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy.

The budget neutrality factors applied for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are built permanently into the capital Federal rate; that is, they are applied cumulatively in determining the capital Federal rate. However, the budget neutrality factor for the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy is not permanently built into the capital Federal rate. This is because the GAFs with 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy applied from the previous year are not used in the budget neutrality factor calculations for the current year. Accordingly, and consistent with this approach, prior to calculating the proposed GAF budget neutrality factors for FY 2027, we removed from the capital Federal rate the budget neutrality factor applied in FY 2026 for the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. Specifically, we divided the capital Federal rate by the FY 2026 budget neutrality factor of 0.9989 (90 FR 37235 through 37236). (We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45552) for additional discussion on our policy of removing from the capital Federal rate the prior year budget neutrality factor(s) that are not used in the budget neutrality factor calculations for the current year.)

We discuss our 2-step calculation of the proposed GAF budget neutrality factors for FY 2027 as follows. To determine the GAF budget neutrality factors for FY 2027, we first compared estimated aggregate capital Federal rate payments based on the FY 2026 MS-DRG classifications and relative weights and the FY 2026 GAFs to estimated aggregate capital Federal rate payments based on the FY 2026 MS-

DRG classifications and relative weights and the FY 2027 GAFs without incorporating the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy. To achieve budget neutrality for these proposed changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 1.0156 for FY 2027.

Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2027 GAFs with and without the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy. For this calculation, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2027 MS-DRG classifications and relative weights (after application of the 10-percent cap discussed later in this section) and the proposed FY 2027 GAFs (both with and without the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy). (We note, for this calculation the GAFs included the imputed floor, out-migration, and Frontier State adjustments.) To achieve budget neutrality for the effects of the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy on the FY 2027 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9913.

The budget neutrality factor for the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy is not permanently built into the capital Federal rate. Consistent with this, we present the budget neutrality factor for the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy calculated under the second step of this 2-step methodology separately from the other budget neutrality factors in the discussion that follows, and this factor is not included in the calculation of the proposed combined GAF/DRG adjustment factor described later in this section.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a permanent 10-percent cap on the reduction in an MS-DRG's relative weight in a given fiscal year, beginning in FY 2023. Consistent with our historical methodology for adjusting the capital standard Federal

rate to ensure that the effects of the annual DRG reclassification and the recalibration of DRG weights are budget neutral under § 412.308(c)(4)(ii), we finalized to apply an additional budget neutrality factor to the capital standard Federal rate so that the 10-percent cap on decreases in an MS-DRG's relative weight is implemented in a budget neutral manner (87 FR 49436). Specifically, we augmented our historical methodology for computing the budget neutrality factor for the annual DRG reclassification and recalibration by computing a budget neutrality adjustment for the annual DRG reclassification and recalibration in two steps. We first calculate a budget neutrality factor to account for the annual DRG reclassification and recalibration prior to the application of the 10-percent cap on MS-DRG relative weight decreases. Then we calculate an additional budget neutrality factor to account for the application of the 10-percent cap on MS-DRG relative weight decreases.

To determine the proposed DRG budget neutrality factors for FY 2027, we first compared estimated aggregate capital Federal rate payments based on the FY 2026 MS-DRG classifications and relative weights to estimated aggregate capital Federal rate payments based on the proposed FY 2027 MS-DRG classifications and relative weights prior to the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2027 GAFs without the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy. The proposed incremental adjustment factor for DRG classifications and changes in relative weights prior to the application of the 10-percent cap is 0.9986. Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2027 MS-DRG classifications and relative weights prior to the application of the 10-percent cap to estimated aggregate capital Federal rate payments based on the proposed FY 2027 MS-DRG classifications and relative weights after the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were also calculated using the proposed FY 2027 GAFs without the 5 percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy. The proposed incremental adjustment factor for the

application of the 10-percent cap on relative weight decreases is 0.9998. Therefore, to achieve budget neutrality for the proposed FY 2027 MS-DRG reclassification and recalibration (including the 10-percent cap), based on the calculations described previously, we applied a proposed incremental budget neutrality adjustment factor of 0.9983 ( $0.9986 \times 0.9998$ ) for FY 2027 to the capital Federal rate. We note that all the values are calculated with unrounded numbers.

The proposed incremental adjustment factor for the proposed FY 2027 MS-DRG reclassification and recalibration (0.9983) and for changes in the proposed FY 2027 GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (1.0156) is 1.0139 ( $0.9983 \times 1.0156$ ). This incremental adjustment factor is built permanently into the capital Federal rates.

To achieve budget neutrality for the effects of the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy on the FY 2027 GAFs, as described previously, we calculated a proposed budget neutrality adjustment factor of 0.9913 for FY 2027. We refer to this proposed budget neutrality factor for the remainder of this section as the cap/transition adjustment factor.

We applied the proposed budget neutrality adjustment factors described previously to the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are determined separately. Under the capital IPPS, there is a single budget neutrality adjustment factor for changes in the GAF that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy. In addition, there is no adjustment for the effects that geographic reclassification, the 5-

percent cap on wage index decreases policy, or the proposed transition for the discontinuation of the low wage index hospital policy described previously have on the other payment parameters, such as the payments for DSH or IME.

The proposed incremental GAF/DRG adjustment factor of 1.0139 accounts for the proposed MS-DRG reclassifications and recalibration (including application of the 10-percent cap on relative weight decreases) and for changes in the proposed GAFs that result from proposed updates to the wage data, the effects on the GAFs of FY 2027 geographic reclassification decisions made by the MGCRB compared to FY 2026 decisions, and the application of the rural floor policy. The proposed cap/transition adjustment factor of 0.9913 accounts for changes that result from the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy. However, these factors do not account for changes in payments due to changes in the DSH and IME adjustment factors.

#### 4. Capital Federal Rate for FY 2027

For FY 2026, we established a capital Federal rate of \$524.15 (90 FR 37236). We are proposing to establish an update of 3.1 percent in determining the FY 2027 capital Federal rate for all hospitals. As a result of this proposed update and the budget neutrality factors discussed earlier, we are proposing to establish a national capital Federal rate of \$545.22 for FY 2027. The proposed national capital Federal rate for FY 2027 was calculated as follows:

- The proposed FY 2027 update factor is 1.031; that is, the proposed update is 3.1 percent.
  - The proposed FY 2027 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS-DRG classifications and relative weights (including application of the 10-percent cap on relative weight decreases) and changes in the GAFs that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy is 1.0139.
  - The proposed FY 2027 cap/transition budget neutrality adjustment factor that is applied to the capital Federal rate for changes due to the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy is 0.9913.
  - The proposed FY 2027 outlier adjustment factor is 0.9642.
- We are providing the following chart that shows how each of the proposed



factors and adjustments for FY 2027 affects the computation of the proposed FY 2027 national capital Federal rate in comparison to the FY 2026 national capital Federal rate. The proposed FY 2027 update factor has the effect of increasing the capital Federal rate by 3.1 percent compared to the FY 2026 capital Federal rate. The proposed GAF/DRG

budget neutrality adjustment factor has the effect of increasing the capital Federal rate by 1.39 percent. The proposed FY 2027 cap/transition budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.77 percent compared to the FY 2026 capital Federal rate. The proposed FY 2027 outlier adjustment factor has

the effect of increasing the capital Federal rate by 0.27 percent compared to the FY 2026 capital Federal rate. The combined effect of all the proposed changes would increase the national capital Federal rate by approximately 4.02 percent, compared to the FY 2026 national capital Federal rate.

## COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2026 CAPITAL FEDERAL RATE AND THE PROPOSED FY 2027 CAPITAL FEDERAL RATE

|                                                   | FY 2026  | FY 2027 | Change | Percent Change    |
|---------------------------------------------------|----------|---------|--------|-------------------|
| Update Factor <sup>1</sup>                        | 1.0280   | 1.0310  | 1.0310 | 3.10              |
| GAF/DRG Adjustment Factor <sup>1</sup>            | 0.9918   | 1.0139  | 1.0139 | 1.39              |
| GAF Cap/Transition Adjustment Factor <sup>2</sup> | 0.9989   | 0.9913  | 0.9923 | -0.77             |
| Outlier Adjustment Factor <sup>3</sup>            | 0.9616   | 0.9642  | 1.0027 | 0.27              |
| Capital Federal Rate                              | \$524.15 | \$45.22 | 1.0402 | 4.02 <sup>4</sup> |

<sup>1</sup> The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rate. Thus, for example, the incremental change from FY 2026 to FY 2027 resulting from the application of the proposed 1.0139 GAF/DRG budget neutrality adjustment factor for FY 2027 is a net change of 1.0139 (or 1.39 percent).

<sup>2</sup> The GAF Cap/Transition budget neutrality adjustment factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2027 GAF Cap/Transition budget neutrality adjustment factor is 0.9913/0.9989 or 0.9923 (or -0.77 percent).

<sup>3</sup> The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2027 outlier adjustment factor is 0.9642/0.9616 or 1.0027 (or 0.27 percent).

<sup>4</sup> Percent change may not sum due to rounding.

### B. Calculation of the Proposed Inpatient Capital Related-Prospective Payments for FY 2027

For purposes of calculating payments for each discharge during FY 2027, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier threshold for FY 2027 is in section II.A. of this Addendum. For FY 2027, a case will qualify as a cost outlier if the cost for the case is greater than the prospective payment rates for the MS-DRG plus IME and DSH payments (including the empirically justified Medicare DSH payment and the estimated uncompensated care payment), estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus the proposed fixed-loss amount of \$51,679.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

### C. Capital Input Price Index

#### 1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect, the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted

average of past capital purchase prices up to and including the current year.

For this proposed rule, we are proposing to use the IPPS operating and capital market baskets that reflect a 2023 base year. For a complete discussion of the rebasing of the IPPS operating and capital market baskets, we refer readers to section IV. of the preamble of the FY 2026 IPPS/LTCH PPS final rule (90 FR 36859 through 36879).

#### 2. Forecast of the CIPI for FY 2027

Based on IHS Global Inc.'s fourth quarter 2025 forecast, for this proposed rule, we are forecasting the 2023-based CIPI to increase 2.8 percent in FY 2027. This reflects a projected 3.3 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), a projected 0.5 percent increase in vintage-weighted interest expense prices and a projected 3.0 percent increase in other capital expense prices in FY 2027. The weighted average of these three factors produces the forecasted 2.8 percent increase for the 2023-based CIPI in FY 2027.

We are also proposing that if more recent data become available (for example, a more recent estimate of the percentage increase in the 2023-based CIPI), we would use such data, if appropriate, to determine the FY 2027 capital update factor for the final rule.



#### IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2027

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are paid on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

For this FY 2027 IPPS/LTCH PPS proposed rule, based on IGI's 2025 fourth quarter forecast, we estimate that the 2023-based IPPS operating market basket percentage increase for FY 2027 is 3.2 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the proposed FY 2027 rate-of-increase percentage that will be applied to the FY 2026 target amounts in order to calculate the proposed FY 2027 target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals is 3.2 percent, in accordance with the applicable regulations at 42 CFR 413.40. We are also proposing that if more recent data become available (for example a more recent estimate of the market basket rate-of-increase), we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2027.

IRFs and rehabilitation distinct part units, IPFs and psychiatric units, and LTCHs are excluded from the IPPS and paid under their respective PPSs. The

IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section IX. of the preamble and section V. of the Addendum of this proposed rule for the changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2027. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

#### V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2027

##### A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2027

##### 1. Overview

In section VIII. of the preamble of this proposed rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2027.

Under § 412.523(c)(3) of the regulations, for FY 2012 and subsequent years, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II) and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xvii)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as discussed in section IX.C.2. of the preamble of this proposed rule. This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VIII.C.2. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term "fiscal year" (FY) rather than "rate year" (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term "fiscal year" rather than "rate year" for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in

accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

##### 2. Development of the Proposed FY 2027 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2027, we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the proposed LTCH PPS standard Federal payment rate for FY 2027, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2027 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data and labor-related share) as discussed in section V.B.6. of this Addendum.

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 2.4 percent (that is, the most recent estimate of the 2022-based LTCH market basket increase of 3.2 percent less the proposed productivity adjustment of 0.8 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are proposing to apply an update factor of 1.024 to the FY 2026 LTCH PPS standard Federal payment rate of \$50,824.51 to determine the proposed FY 2027 LTCH PPS standard Federal payment rate. Also, in accordance with § 412.523(c)(3)(xvii) and (c)(4), we are required to reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for LTCHs that fail to submit the required quality reporting data for FY 2027 as required under the LTCH QRP. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.4 percent (or an update factor of 1.004). This proposed update reflects the proposed annual market basket update of 3.2 percent reduced by the proposed 0.8 percentage point productivity adjustment, as required by section 1886(m)(3)(A)(i) of the Act, minus 2.0 percentage points for LTCHs failing to submit quality data under the LTCH QRP, as required by section 1886(m)(5) of the Act. Consistent with § 412.523(d)(4), we are proposing to apply an area wage level budget neutrality factor to the FY 2027 LTCH PPS standard Federal payment rate of

1.0025505, based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index (including application of the 5-percent cap on wage index decreases, discussed later in this section), and proposed labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are proposing to establish an LTCH PPS standard Federal payment rate of \$52,177.04 (calculated as  $\$50,824.51 \times 1.024 \times 1.0025505$ ) for FY 2027. For LTCHs that fail to submit quality reporting data for FY 2027, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of \$51,157.95 (calculated as  $\$50,824.51 \times 1.004 \times 1.0025505$ ) for FY 2027.

#### *B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2027*

##### 1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The proposed FY 2027 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2026, through September 30, 2027, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of this Addendum and available via the internet on the CMS website.

##### 2. Proposed Geographic Classifications (Labor Market Areas) under the LTCH PPS

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH

is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an “urban area,” or a “rural area,” as defined in § 412.503. Under § 412.503, an “urban area” is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by OMB, and a “rural area” is defined as any area outside of an urban area.

The geographic classifications (labor market area definitions) currently used under the LTCH PPS are based on the Core Based Statistical Areas (CBSAs) established by OMB. In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Community Survey. In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (“the 2020 Standards”), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). A copy of OMB Bulletin No. 23–01 may be obtained at <https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf>.

In the FY 2025 IPPS/LTCH PPS final rule, we stated that we believe that adopting the CBSA-based labor market area delineations established in OMB Bulletin 23–01 will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (89 FR 69974). We also noted that our adoption of the revised delineations announced in OMB Bulletin No. 23–01 is consistent with the changes under the IPPS for FY 2025. Therefore, in that same final rule, we adopted the updates set forth in OMB Bulletin No. 23–01, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, for the LTCH PPS effective for FY 2025. We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69973 through

69975), for a full discussion of our implementation of the OMB delineations based on OMB Bulletin No. 23–01 for the LTCH PPS. For additional information on the CBSA-based labor market area (geographic classification) delineations used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).

We continue to believe that the CBSA-based labor market area delineations, as established in OMB Bulletin 23–01, would ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (89 FR 69974). Therefore, for FY 2027, we are proposing to continue to use the CBSA-based labor market area delineations as established in OMB Bulletin 23–01 and adopted in the FY 2025 IPPS/LTCH final rule.

CBSAs are made up of one or more constituent counties. For FY 2027, we are proposing to continue using the Federal Information Processing Standard (FIPS) county codes, maintained by the U.S. Census Bureau, for purposes of crosswalking counties to CBSAs. The current county-to-CBSA crosswalk was adopted under the LTCH PPS in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69973 through 69975) and is located on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/long-term-care-hospital/other-files-download>.

##### 3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and

27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

Effective FY 2025, we rebased and revised the 2017-based LTCH market basket to reflect a 2022 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2022-based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69435 through 69455).)

In this proposed rule, consistent with our historical practice, we are proposing that the LTCH PPS labor-related share for FY 2027 would be the sum of the FY 2027 relative importance of each labor-related cost category in the LTCH market basket using the most recent available data. Specially, we are proposing that the labor-related share for FY 2027 is the sum of the labor-related portion of operating costs from the 2022-based LTCH market basket (that is, the sum of the FY 2027 relative importance shares of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services) and a portion of the relative importance of Capital-Related cost weight from the 2022-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2022) and FY 2027. Based on IHS Global Inc.'s fourth quarter 2025 forecast of the 2022-based LTCH market basket, the sum of the FY 2027 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-Related Services was 69.1 percent. The portion of capital-related costs that is influenced by the local labor market was estimated to be 46 percent (that was, the same percentage applied to the 2009-based, 2013-based, and 2017-based LTCH market basket capital-related costs relative importance). Since the FY 2027 relative importance for capital-related costs was 8.4 percent based on IHS Global Inc.'s fourth quarter 2025 forecast of the 2022-based LTCH market basket, we took 46 percent of 8.4 percent to determine the labor-related share of capital-related costs for FY 2027 of 3.9 percent. Therefore, we are proposing a total labor-related share for FY 2027 of 73.0 percent (the sum of 69.1 percent for the labor-related share of operating costs and 3.9 percent for the

labor-related share of capital-related costs). Consistent with our historical practice, we are proposing that if more recent data become available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the relative importance of each labor-related cost category of the 2022-based LTCH market basket), we would use such data, if appropriate, to determine the FY 2027 LTCH PPS labor-related share.

#### 4. Proposed Wage Index for FY 2027 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the "urban" or "rural" designation of any related or affiliated provider. As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also employ a policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2027 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to continue to employ our historical practice of using the same data we used to compute the proposed FY 2027 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule (that is, wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2023) because these data are the most recent complete data available.

In addition, we are proposing to compute the FY 2027 LTCH PPS standard Federal payment rate area wage index values consistent with the "urban" and "rural" geographic classifications (that is, the proposed labor market area delineations as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. We are also proposing to

continue to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2027, we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2023 IPPS wage data that we are proposing to use to determine the FY 2027 LTCH PPS area wage index values in this proposed rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with our existing methodology, we calculated the proposed FY 2027 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, proposed CBSAs 10500, 12020, 12054, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 31924, 40660, 42340, 46660, and 47580), as shown in Table 12A, which is listed in section VI. of this Addendum.

Based on the FY 2023 IPPS wage data that we are proposing to use to determine the FY 2027 LTCH PPS area wage index values in this proposed rule, there are no IPPS wage data for rural North Dakota (CBSA 35). Consistent with our existing methodology, we calculated the proposed FY 2027 wage index value for CBSA 35 as the average of the wage index values for all proposed CBSAs that are contiguous to the rural counties of the State (that is, proposed CBSAs 13900, 22020, 24220, and 33500), as shown in Table 12B, which is listed in section VI. of this Addendum. We note that, as IPPS wage data are dynamic, it is possible that the number of urban and rural areas without IPPS wage data will vary in the future.

#### 5. Cap on Wage Index Decreases

##### a. Cap on LTCH PPS Wage Index Decreases

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49440 through 49442), we finalized a policy that applies a permanent 5-percent cap on any

decrease to an LTCH's wage index from its wage index in the prior year. Consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner, we include the application of this policy in the determination of the area wage level budget neutrality factor that is applied to the standard Federal payment rate, as is discussed later in section V.B.6. of this Addendum.

Under this policy, an LTCH's wage index will not be less than 95 percent of its wage index for the prior fiscal year. An LTCH's wage index cap adjustment is determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year, these LTCHs will not be subject to the LTCH PPS wage index cap since they were not paid under the LTCH PPS in the prior year. For example, newly opened LTCHs that become operational during FY 2027 would not be eligible for the LTCH PPS wage index cap in FY 2027. These LTCHs would receive the calculated wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage index cap. The cap on wage index decreases policy is reflected at § 412.525(c)(1).

For each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped wage index. This includes the LTCH's final prior year wage index value, the LTCH's uncapped current year wage index value, and the LTCH's capped current year wage index value. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact their MAC to ensure that its wage index value is not less than 95 percent of the value paid to it for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this proposed rule at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>.

#### b. Cap on IPPS Comparable Wage Index Decreases

Determining LTCH PPS payments for short-stay-outlier cases (reflected in § 412.529) and site neutral payment rate cases (reflected in § 412.522(c)) requires calculating an "IPPS comparable amount." For information on this "IPPS

comparable amount" calculation, we refer the reader to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49608 through 49610). Determining LTCH PPS payments for LTCHs that do not meet the applicable discharge payment percentage (reflected in § 412.522(d)) requires calculating an "IPPS equivalent amount." For information on this "IPPS equivalent amount" calculation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439 through 42445).

Calculating both the "IPPS comparable amount" and the "IPPS equivalent amount" requires adjusting the IPPS operating and capital standardized amounts by the applicable IPPS wage index for nonreclassified IPPS hospitals. That is, the standardized amounts are adjusted by the IPPS wage index for nonreclassified IPPS hospitals located in the same geographic area as the LTCH. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49442 through 49443), we finalized a policy that applies a permanent 5-percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year. Historically, we have not budget neutralized changes to LTCH PPS payments that result from the annual update of the IPPS wage index for nonreclassified IPPS hospitals. Consistent with this approach, the cap on decreases in an LTCH's applicable IPPS comparable wage index is not applied in a budget neutral manner.

Under this policy, an LTCH's applicable IPPS comparable wage index will not be less than 95 percent of its applicable IPPS comparable wage index for the prior fiscal year. An LTCH's applicable IPPS comparable wage index cap adjustment is determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year, these LTCHs will not be subject to the applicable IPPS comparable wage index cap since they were not paid under the LTCH PPS in the prior year. For example, newly opened LTCHs that become operational during FY 2027 would not be eligible for the applicable IPPS comparable wage index cap in FY 2027. This means that these LTCHs would receive the calculated applicable IPPS comparable wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage cap. The cap on IPPS comparable wage index decreases policy is reflected at § 412.529(d)(4)(ii)(B) and (d)(4)(iii)(B).

Similar to the information we are making available for the cap on the LTCH PPS wage index values (described previously), for each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped applicable IPPS comparable wage index. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact its MAC to ensure that its applicable IPPS comparable wage index value is not less than 95 percent of the value paid to them for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this proposed rule at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>.

#### 6. Proposed Budget Neutrality Adjustments for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2027, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level budget neutrality factor to adjust the LTCH PPS

standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). As discussed in section V.B.5. of this Addendum, consistent with, § 412.525(c)(2), we include the application of the 5-percent cap on wage index decreases in the determination of the proposed area wage level budget neutrality factor. Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2027 using the following methodology:

*Step 1*—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2026 wage index values and the FY 2026 labor-related share of 72.9 percent.

*Step 2*—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the proposed FY 2027 wage index values (including the application of the 5-percent cap on wage index decreases) and the proposed FY 2027 labor-related share of 73.0 percent. (As noted previously, the proposed changes to the wage index values based on updated hospital wage data are discussed in section V.B.4. of this Addendum and the proposed labor-related share is discussed in section V.B.3. of this Addendum.)

*Step 3*—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2026 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2027 updates to the area wage level adjustment (calculated in Step 2) to determine the proposed budget neutrality factor for updates to the area wage level adjustment for FY 2027 LTCH PPS standard Federal payment rate payments.

*Step 4*—Apply the proposed FY 2027 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2027 LTCH PPS standard Federal payment rate after the application of the proposed FY 2027 annual update.

We are proposing to use the most recent data available, including claims from the FY 2025 MedPAR file, in calculating the FY 2027 LTCH PPS standard Federal payment rate area

wage level adjustment budget neutrality factor. We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the FY 2027 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor.

For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2027 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0025505. Accordingly, in section V.A. of this Addendum, we applied the proposed area wage level adjustment budget neutrality factor of 1.0025505 to determine the proposed FY 2027 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

#### *C. Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii*

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels.

For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) website at <https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/#url=COLA-Rates> to update this nonlabor portion.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by OPM every 4 years (coinciding with the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28019 through 28020 and 77 FR 53481 through 53482, respectively). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45559 through 45560), we updated the COLA factors published by OPM for 2009 (as these are the last

COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and Consumer Price Indices (CPIs) data through 2020. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we utilized these COLA factors for FYs 2022 through 2025 to adjust the nonlabor-related portion of the standard Federal payment rate for LTCHs located in Alaska and Hawaii.

In general, under our existing methodology, we update the 2009 OPM COLA factors by a comparison of the growth in the CPIs for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We use the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively, because BLS publishes CPI data for only Urban Alaska and Urban Hawaii. Using the respective CPI commodities index and CPI services index and using the approximate commodities/services shares obtained from the IPPS market basket, we create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. Lastly, we exercised our discretionary authority to adjust payments to LTCHs in Alaska and Hawaii by incorporating the statutorily mandated cap of 25 percent that was applied when determining OPM's COLA factors. (For additional information, refer to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45559 through 45560).)

We previously stated our intention to update the COLA factors at the same time as the update to the labor-related share of the IPPS market basket. In the FY 2026 IPPS/LTCH PPS proposed rule, we proposed to update the labor-related share of the IPPS market basket. We also stated that at that time, we believed it would be appropriate to maintain the current COLA factors for FY 2026 to allow us to consider whether it would be appropriate to incorporate additional data sources or other methodology changes in determining the COLA factors we apply to LTCH PPS payments to account for the unique circumstances of LTCHs located in Alaska and Hawaii (90 FR 18448 through 18449). Therefore, we proposed to continue to use the FY 2025 COLA factors to adjust the nonlabor-related portion of the standard Federal payment rate for LTCHs located in Alaska and Hawaii for FY 2026. We solicited comments on any possible data

sources that could be considered in the development of the COLA factors.

Although we received no comments on our FY 2026 LTCH PPS proposal, one commenter, as summarized in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37230), supported CMS' proposal to maintain the current COLA methodology under the IPPS temporarily while we evaluate alternative approaches. The commenter requested that CMS utilize a more sensitive adjustment to reflect cost variation across Alaska. The commenter stated that tying Alaska's COLA to a single urban index does not reflect higher costs in more remote areas. The commenter also requested that CMS reconsider the 25-percent cap on the COLAs and engage with providers during the development of the new methodology. After consideration of the public comment we received, we finalized our proposal to continue to use the FY 2025 COLA factors to adjust the nonlabor-related portion of the standard Federal payment rate for LTCHs located in Alaska and Hawaii for FY 2026.

After further consideration and consistent with the approach proposed under the IPPS, effective for FY 2027, we are proposing to adjust non-labor related costs for LTCHs located in Alaska and Hawaii, using the Overseas Cost-of-Living Allowance (OCOLA) data<sup>563</sup> published by the Department of Defense (DOD). These OCOLAs are received by Service members serving outside of the contiguous U.S. (OCONUS) and are designed to offset higher prices of non-housing goods and services in order to equalize purchasing power with members stationed in the contiguous U.S. (CONUS). To calculate the OCOLAs for each OCONUS area, DOD currently uses Living Pattern Survey (LPS) data on purchasing patterns of Service members (*e.g.* how and where they purchase certain goods and services including whether these are purchased from a commissary, retail store, or online) and price data for approximately 150 goods and services.<sup>564</sup> The DOD compares the

OCONUS LPS and price data with similar data obtained in CONUS.

We believe the DOD OCOLAs are an appropriate data source to capture the cost differences of LTCH nonlabor-related inputs purchased in the areas of Hawaii and Alaska compared to the continental U.S. The DOD OCOLAs reflect the relative price differences in a basket of non-housing goods and services that would be consistent with many of the nonlabor-related goods and services that LTCHs purchase (such as pharmaceuticals, food, and cleaning supplies). In addition, unlike the prior approach that relied on CPI data for urban areas, these relative price differences would account for the additional shipping costs to remote areas. Specifically, the DOD OCOLAs are reflective of the specific areas of Alaska and Hawaii where LTCHs are located.

For the proposed COLA factors for LTCHs located in Alaska and Hawaii for FY 2027, we are proposing to use the OCOLAs published by DOD effective for January 1, 2026. The DOD OCOLAs are available for 26 Alaska locality areas and 6 Hawaii locality areas. Similar to the COLAs used for Alaska and Hawaii for FY 2022 through FY 2026 that are based on the original OPM COLAs, we are proposing to continue to use the four Nonforeign COLA Areas designated by OPM for Alaska and the four Nonforeign COLA Areas designated by OPM for Hawaii as shown in Table V.C.1.

For each of the designated OPM areas for cities in Alaska (City of Anchorage, City of Fairbanks, and City of Juneau), if there is more than one DOD OCOLA within a 50-mile radius of the city, we are proposing to average the DOD OCOLAs within the designated OPM area to calculate the proposed COLA. Specifically, for the COLA factor for the City of Anchorage, we are proposing to average the DOD OCOLAs for the Anchorage and Wasilla locality areas. For the COLA factor for the City of Fairbanks, we are proposing to average the DOD OCOLAs for the College, Eielson Air Force Base, and Fairbanks locality areas. For the Rest of Alaska COLA, given that there are IPPS hospitals located in two locality areas (Bethel and Kenai), we are proposing to average the DOD OCOLAs for these two locality areas to calculate the proposed COLA. We note there is currently only

one LTCH in Alaska, located in Anchorage.

For Hawaii, the OCOLAs published by DOD are generally consistent with the OPM designated areas. To obtain the COLA factor for the OPM designated area of County of Maui and County of Kalawao, we are proposing to average the DOD OCOLAs for the Maui and Molokai locality areas. We note there are currently no LTCHs located in Hawaii.

Starting with the FY 2027 payment year, we are proposing to no longer cap the COLA factors at 25 percent. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent<sup>565</sup> and we had exercised our discretionary authority to adjust payments to LTCHs in Alaska and Hawaii by incorporating this 25-percent cap. Since we are no longer proposing to use the OPM COLA factors, we are exercising our discretionary authority to no longer cap the COLA factors at 1.25. Lastly, for fiscal years after FY 2027, in order to facilitate stability in payment rates, we are proposing to continue to update the COLA factors at the same time the labor-related share of the IPPS market basket is updated.

Below is a table with the proposed COLA factors for FY 2027, as calculated using this proposed methodology, which indicates that changing the data source and eliminating the 25-percent cap has different impacts by area. We are soliciting comments on this proposed methodology and the use of the DOD OCOLAs, including any comments on how the use of survey data that are specific to Service members, including their access to discounted commissary prices that might be variable by geographic area, may result in differential impacts across the designated areas. We are also requesting comment on any potential modifications to this proposed methodology, including a potential phase-in of the use of these data or a transition period for implementation, which we may consider finalizing in the FY 2027 IPPS/LTCH PPS final rule, after consideration of the comments received.

<sup>563</sup> <https://www.travel.dod.mil/Allowances/Overseas-Cost-of-Living-Allowance/>.

<sup>564</sup> Previously, pricing data was collected by Country Allowance Coordinators in each OCONUS location using the Retail Price Schedule. Effective August 2025, the DOD has outsourced the pricing data collection process for OCONUS to a private contractor.

<sup>565</sup> Section 5941 of title 5, United States Code, and Executive Order 10000 (as amended) authorize the payment of COLAs in nonforeign areas (<https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/>) and states that the allowance may not exceed 25 percent.

**TABLE V.C.1: PROPOSED COST-OF LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2027**

| Arcas                                                       | FY 2022 to FY 2026 | Proposed FY 2027 |
|-------------------------------------------------------------|--------------------|------------------|
| Alaska:                                                     |                    |                  |
| City of Anchorage and 80-kilometer (50-mile) radius by road | 1.22               | 1.28             |
| City of Fairbanks and 80-kilometer (50-mile) radius by road | 1.22               | 1.32             |
| City of Juneau and 80-kilometer (50-mile) radius by road    | 1.22               | 1.36             |
| Rest of Alaska                                              | 1.24               | 1.44             |
| Hawaii:                                                     |                    |                  |
| City and County of Honolulu                                 | 1.25               | 1.20             |
| County of Hawaii                                            | 1.22               | 1.32             |
| County of Kauai                                             | 1.25               | 1.26             |
| County of Maui and County of Kalawao                        | 1.25               | 1.24             |

#### *D. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases*

##### 1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we

adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

To maintain budget neutrality, consistent with the budget neutrality requirement at § 412.523(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).

##### 2. Determining LTCH CCRs Under the LTCH PPS

###### a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and are also used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a

single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding CCRs and HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs in excess of the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

###### b. LTCH Total CCR Ceiling

Consistent with our historical practice, we are proposing to use the best available data to determine the LTCH total CCR ceiling for FY 2027 in this proposed rule. Specifically, in this



proposed rule, we are proposing to use our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2025 update of the Provider Specific File (PSF), which is the most recent data available. Accordingly, we are proposing an LTCH total CCR ceiling of 1.354 under the LTCH PPS for FY 2027 in accordance with § 412.525(a)(4)(iv)(C)(2) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. Consistent with our historical practice, we are proposing to use the best available data, if applicable, to determine the LTCH total CCR ceiling for FY 2027 in the final rule. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48117 through 48119).)

#### c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on “total” IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital’s provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH’s CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this

proposed rule, we are proposing to use our established methodology for determining the LTCH PPS statewide average CCRs, based on the most recent complete IPPS “total CCR” data from the December 2025 update of the PSF. We are proposing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2026, through September 30, 2027, in Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website). Consistent with our historical practice, we also are proposing to use the best available data, if applicable, to determine the LTCH PPS statewide average total CCRs for FY 2027 in the final rule.

Under the current LTCH PPS labor market areas, all areas in the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are proposing to use this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

Furthermore, although Connecticut, Idaho, Massachusetts, Nevada, and North Dakota have areas that are designated as rural under the current LTCH PPS labor market areas, in our calculation of the LTCH statewide average CCRs, there were no trimmed CCR data available from IPPS hospitals located in these rural areas as of December 2025. We refer the reader to section II.A.4.i.(2). of this Addendum for details on the trims applied to the IPPS CCR data from the December 2025 update of the PSF, which are the same data used to calculate the LTCH statewide average total CCRs. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut,

Idaho, Massachusetts, Nevada, and North Dakota in Table 8C. We note that there were no LTCHs located in these rural areas as of December 2025.

#### d. Reconciliation of HCO Payments

Under the HCO policy at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation (regardless of whether payment is based on the LTCH standard Federal payment rate or the site neutral payment rate). Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821), and most recently modified by Change Request 14233 (Transmittal 13428; September 22, 2025) with an update to the outlier reconciliation criteria.

#### 3. Proposed High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

##### a. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

##### b. Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2027

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments (that is, the target percentage) under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general,



the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

For this proposed rule, for the reasons discussed below, we are proposing to depart from our historical methodology for determining the fixed-loss amount, which we used to determine the FY 2026 fixed-loss amount in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37243 through 37247). Under our historical methodology, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been an LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. Due to the lag time in the availability of claims data, under our historical methodology, we inflate charges from the claims data by a uniform factor based on the historical growth in charges for LTCH PPS standard Federal payment rate cases. We then multiply the inflated charges by each provider's best available CCR, which has been adjusted by a factor calculated from historical changes in the average case-weighted CCR for LTCHs. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

On September 22, 2025, we issued Change Request (CR) 14233, which is available at <https://www.cms.gov/medicare/regulations-guidance/transmittals/2025-transmittals/r13428cp>. CR 14233 provides additional instructions to MACs that expand the criteria for identifying cost reports. MACs are to refer to CMS for approval of outlier reconciliation. The original criteria issued in July 2003 instructed MACs to identify for CMS any instances where: (1) the actual CCR is found to be plus or minus 10 percentage points from the CCR used during that cost reporting period to make outlier payments, and (2) the total outlier payments exceeded \$500,000 for that cost reporting period.

CR 14233 expanded this criteria for cost reports beginning on or after October 1, 2025, by instructing MACs to also identify for CMS any instances where: (1) the actual CCR is found to be plus or minus 20 percent or more from the CCR used during that time period to make outlier payments, and (2) the total outlier payments exceeded \$500,000 for that cost reporting period.

We analyzed the FY 2023 cost reports to better understand the potential impact the expanded criteria would have on LTCH payments. We found that approximately 2 percent of LTCH cost reports met the original reconciliation criteria, while approximately 24 percent of LTCH cost reports would have met the expanded reconciliation criteria. For the vast majority of the cost reports that would have met the expanded criteria, the LTCHs increased their charges during their cost reporting period at rates that far exceed their costs. This practice of significant year-over-year charge increases has been documented in the charge inflation factors we have calculated in recent rules. (As an example, in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37246), we determined that LTCHs, on average, increased their charges approximately 13 percent from FY 2023 to FY 2024.) Based on the most recent data available for this proposed rule, we determined that LTCHs, on average, increased their charges approximately 17 percent from FY 2024 to FY 2025.

As discussed in greater detail below, we do not believe our historical methodology, which relies on the most recently available data, would accurately estimate outlier payments for LTCHs in FY 2027. Ordinarily, the best available data to use for ratesetting is the most recently available data. However, in light of the issuance of CR 14233, we do not believe the most recently available data for estimating outlier payments is reflective of the expected LTCH experience in FY 2027. With an incentive to avoid outlier reconciliation, we believe LTCHs will not continue to increase their charges relative to costs at the rates reflected in the most recently available data. Specifically, we do not believe the recent annual increase in average charges of approximately 17 percent is a reliable indicator for forecasting future annual increases in charges that will occur for purposes of estimating outlier payments in FY 2027. Similarly, we do not believe the historical changes in LTCHs' CCRs observed from cost reporting periods subject to only the original criteria can be used to reliably predict future CCR levels for purposes of estimating outlier payments in FY

2027. However, we currently lack sufficient information to reasonably quantify the magnitude a behavioral change would have on charging practices and outlier payment trends in FY 2027. Using a variety of assumptions for charge inflation and degree of outlier reconciliation, we estimated that a fixed-loss amount that would meet the statutory budget neutral target of estimated LTCH PPS outlier payments in FY 2027 would fall in the range of approximately \$67,000 (a decrease of approximately \$12,000 compared to the current fixed-loss amount) to \$109,000 (an increase of approximately \$30,000 compared to the current fixed-loss amount). Given this wide range of uncertainty in attempting to adopt assumptions about charge inflation and degree of outlier reconciliation for purposes of estimating the fixed-loss amount for FY 2027 and the aforementioned issues with using the historic methodology for purposes of estimating the fixed-loss amount for FY 2027, we believe that maintaining the fixed-loss amount at its FY 2026 level is a reasonable estimate of a fixed-loss amount that will result in estimated LTCH PPS outlier payments being equal to 7.975 percent of total LTCH PPS payments for FY 2027. Therefore, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are proposing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2027 of \$78,936 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2027 payments for such cases. As such, we will make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of \$78,936). We believe setting the FY 2027 fixed-loss amount at the FY 2026 level will provide stability and predictability while allowing CMS time to gain insight into LTCHs' response to the additional reconciliation criteria. We intend to reassess the appropriateness of returning to our historical calculation methodology for future years as more representative data becomes available.

#### 4. Proposed High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment

rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FYs 2019 through 2025, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases and the provisions of section 3711(b)(2) of the CARES Act, the historical claims data available in each of these years were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2025, our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS-DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use

of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2025 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2025.

In the FY 2026 IPPS/LTCH PPS final rule (90 FR 37247) we discussed that section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases. This waiver applied to patients admitted during the COVID-19 PHE period and expired on May 11, 2023. Although the vast majority of LTCH discharges in FY 2024 were not subject to the waiver of the application of the site neutral payment rate, we believed LTCHs' admission patterns may still have been adapting to the expiration of the waiver of the application of the site neutral payment rate. Therefore, we did not believe it was appropriate to use FY 2024 data to develop a fixed-loss amount for site neutral payment rate cases for FY 2026. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the FY 2026 IPPS fixed-loss amount of \$40,397 (90 FR 37247).

For FY 2027, we are proposing to set the fixed-loss amount for site neutral payment rate cases equal to the FY 2027 IPPS fixed-loss amount. As discussed above, the waiver of the application of the site neutral payment rate under section 3711(b)(2) of the CARES Act expired on May 11, 2023. While FY 2024 and FY 2025 claims data reflect discharges that were not subject to this waiver, we believe that only two years of data subject to the full application of the site neutral payment rate is not sufficient for establishing a separate methodology for determining the fixed-loss amount for site neutral payment rate cases. We remain concerned that LTCH admission patterns may still be evolving following the expiration of the PHE waiver, and that adjusting our current policy based on this limited period of data would not be appropriate. We will continue to monitor claims data in future years to assess whether

adjustments to this policy may be warranted as we accumulate a more robust dataset reflecting the post-PHE environment.

Accordingly, for FY 2027, we are proposing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we are proposing a fixed-loss amount for site neutral payment rate cases of \$51,679, which is the same FY 2027 IPPS fixed-loss amount discussed in section II.A.4.i.(2). of this Addendum.

Accordingly, under this policy, for FY 2027, we would calculate an HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of \$51,679).

In establishing an HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2027 would not result in any increase in estimated aggregate FY 2026 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2027. Consistent with our historical practice, we are proposing to continue this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the proposed fixed-loss threshold would result in FY 2027 HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2027 would not result in any increase in estimated aggregate FY 2027 LTCH PPS payments, under the budget neutrality requirement

at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2027. To achieve this, for FY 2027, we are proposing to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as  $1.0 - 5.1/100 = 0.949$ ) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this proposed HCO budget neutrality adjustment will not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

*E. Proposed Update to the IPPS Comparable Amount to Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology*

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the “IPPS comparable amount” under the SSO policy at § 412.529 and the “IPPS equivalent amount” under the site neutral payment rate at § 412.522. Historically, the determination of both the “IPPS comparable amount” and the “IPPS equivalent amount” includes an amount for inpatient operating costs “for the costs of serving a disproportionate share of low-income patients.” Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under the age of 65 who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital’s amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all

hospitals that receive Medicare DSH payments.

To reflect the Medicare DSH payment adjustment methodology statutory changes in section 3133 of the Affordable Care Act in the calculation of the “IPPS comparable amount” and the “IPPS equivalent amount” under the LTCH PPS, we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766) that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the “IPPS comparable amount” and the “IPPS equivalent amount” under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2027, as discussed in greater detail in section IV.E.2.b. of the preamble of this proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 65.00 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2027. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 48.75 percent (the product of 75 percent and 65.00 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As

a result, for FY 2027, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 73.75 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 48.75 percent = 73.75 percent). Therefore, for FY 2027, we are proposing to establish that the calculation of the “IPPS comparable amount” under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 73.75 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we are proposing that, if more recent data became available, we would use that data to determine the applicable operating Medicare DSH payment amount used to calculate the “IPPS comparable amount” in the final rule.

*F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2027*

Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages; we make this adjustment by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the proposed FY 2027 values are shown in Tables 12A through 12B listed in section VI. of this Addendum and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2027 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish an LTCH PPS standard Federal payment rate for FY 2027 of \$52,177.04, as discussed in section V.A. of this Addendum. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal payment

rate for FY 2027, applying our proposed LTCH PPS amounts for the standard Federal payment rate, MS–LTC–DRG relative weights, and wage index in the following example:

*Example:*

During FY 2027, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a proposed FY 2027 LTCH PPS wage index value of 1.0107 (as shown in Table 12A listed in section VI. of this Addendum). The Medicare patient case is classified into proposed MS–LTC–DRG 189 (Pulmonary Edema &

Respiratory Failure), which has a proposed relative weight for FY 2027 of 0.9688 (as shown in Table 11 listed in section VI. of this Addendum). The LTCH submitted quality reporting data for FY 2027 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted proposed Federal prospective payment for this Medicare patient case in FY 2027, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed FY 2027 LTCH PPS standard Federal payment rate (\$52,177.04) by the proposed labor-related share (73.0

percent) and the proposed wage index value (1.0107). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (27.0 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9688) to calculate the total adjusted proposed LTCH PPS standard Federal payment for FY 2027 (\$50,943.95). The table illustrates the components of the calculations in this example.

### EXAMPLE: LTCH'S TOTAL ADJUSTED PROPOSED FEDERAL PROSPECTIVE PAYMENT

|                                                                                                       |               |
|-------------------------------------------------------------------------------------------------------|---------------|
| Unadjusted Proposed LTCH PPS Standard Federal Prospective Payment Rate                                | \$52,177.04   |
| Proposed Labor-Related Share                                                                          | x 0.730       |
| Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate                          | = \$38,089.24 |
| Proposed Wage Index (CBSA 16984)                                                                      | x 1.0107      |
| Proposed Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate                      | = \$38,496.79 |
| Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate (\$52,177.04 x 0.270) | + \$14,087.80 |
| Adjusted Proposed LTCH PPS Standard Federal Payment Amount                                            | = \$52,584.59 |
| Proposed MS-LTC-DRG 189 Relative Weight                                                               | x 0.9688      |
| Total Adjusted Proposed LTCH PPS Standard Federal Prospective Payment                                 | = \$50,943.95 |

#### VI. Tables Referenced in This Proposed Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this proposed rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2026, for the FY 2027 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be on the CMS website. Specifically, all IPPS tables listed in the proposed rule, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available on the CMS website. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules.

Tables 7A and 7B historically contained the Medicare prospective payment system selected percentile lengths of stay for the MS–DRGs for the prior year and upcoming fiscal year. We note, in the FY 2023 IPPS/LTCH PPS

final rule (87 FR 49452), we finalized beginning with FY 2023, to provide the percentile length of stay information previously included in Tables 7A and 7B in the supplemental AOR/BOR data file. The AOR/BOR files can be found on the FY 2027 IPPS proposed rule home page on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>.

As discussed in section II.E.6. of the preamble to this proposed rule, for certain FY 2027 new technology add-on payment applications, we are making available separate tables listing the ICD–10–PCS codes or ICD–10–CM codes that would be used to identify cases relevant to the Breakthrough Device-designated indications, or would be appropriate to exclude for cases related to a different technology, for purposes of the new technology add-on payment, if approved, in Table 10 associated with this proposed rule.

After hospitals have been given an opportunity to review and correct their calculations for FY 2027, we will post Table 15 (which will be available via the CMS website) to display the final FY 2027 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October

1, 2026. We expect Table 15 will be posted on the CMS website in the Fall 2026.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified in this proposed rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this proposed rule are generally available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. Click on the link on the left side of the screen titled “FY 2027 IPPS Proposed Rule Home Page” or “Acute Inpatient -Files-for Download.”

Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2027 Proposed Rule

Table 3.—Proposed Wage Index Table by CBSA—FY 2027 Proposed Rule

Table 4A.—Proposed List of Counties Eligible for the Out-Migration

Adjustment under Section 1886(d)(13) of the Act—FY 2027 Proposed Rule

Table 4B.—Proposed Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2027 Proposed Rule

Table 5.—Proposed List of Medicare Severity Diagnosis-Related Groups

(MS-DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2027 Proposed Rule

Table 6A.—New Diagnosis Codes—FY 2027

Table 6B.—New Procedure Codes—FY 2027

Table 6C.—Invalid Diagnosis Codes—FY 2027

Table 6D.—Invalid Procedure Codes—FY 2027

Table 6E.—Revised Diagnosis Code Titles—FY 2027

Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2027

Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2027

Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2027

Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2027

Table 6I.1.—Proposed Additions to the MCC List—FY 2027

Table 6J.1.—Proposed Additions to the CC List—FY 2027

Table 6J.2.—Proposed Deletions to the CC List—FY 2027

Table 6P.—ICD-10-CM and ICD-10-PCS Codes for Proposed MS-DRG Changes—FY 2027 (Table 6P contains multiple tables, 6P.1a. through 5b. that include the ICD-10-CM and ICD-10-PCS code lists relating to specific proposed MS-DRG changes or other analyses). These tables are referred to throughout section II.C. of the preamble of this proposed rule.

Table 8A.—Proposed FY 2027 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural) —FY 2027 Proposed Rule

Table 8B.—Proposed FY 2027 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals —FY 2027 Proposed Rule

Table 10.—Relevant ICD-10 Codes for Certain FY 2027 New Technology Add-On Payment Applications

Table 16.—Proposed Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2027

Table 18.—Proposed FY 2027 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2027 proposed rule are available through the internet on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html> under the list item for Regulation Number CMS-1849-P:

Table 8C.—Proposed FY 2027 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural) —FY 2027 Proposed Rule

Table 11.—Proposed MS-LTC-DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2026, through September 30, 2027—FY 2027 Proposed Rule

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2026, through September 30, 2027—FY 2027 Proposed Rule

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2026, through September 30, 2027—FY 2027 Proposed Rule

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**TABLE 1A.— PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (66.0 PERCENT LABOR SHARE/34.0 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2027 PROPOSED RULE**

| Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.4 Percent) |            | Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.0 Percent) |            | Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.6 Percent) |            | Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.8 Percent) |            |
|-------------------------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------|------------|------------------------------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------------|------------|
| Labor                                                                               | Nonlabor   | Labor                                                                                   | Nonlabor   | Labor                                                                                    | Nonlabor   | Labor                                                                                         | Nonlabor   |
| \$4,598.80                                                                          | \$2,369.07 | \$4,491.02                                                                              | \$2,313.54 | \$4,562.87                                                                               | \$2,350.56 | \$4,455.09                                                                                    | \$2,295.04 |

**TABLE 1B.— PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2027 PROPOSED RULE**

| Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.4 Percent) |            | Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.0 Percent) |            | Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.6 Percent) |            | Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.8 Percent) |            |
|-------------------------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------|------------|------------------------------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------------|------------|
| Labor                                                                               | Nonlabor   | Labor                                                                                   | Nonlabor   | Labor                                                                                    | Nonlabor   | Labor                                                                                         | Nonlabor   |
| \$4,320.08                                                                          | \$2,647.79 | \$4,218.83                                                                              | \$2,585.73 | \$4,286.33                                                                               | \$2,627.10 | \$4,185.08                                                                                    | \$2,565.05 |

**TABLE 1C.— PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2027 PROPOSED RULE**

|                       | Rates if Wage Index Greater Than 1 |                | Hospital is a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 2.4 Percent) |            | Hospital is NOT a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 0.0 Percent) |            |
|-----------------------|------------------------------------|----------------|-------------------------------------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------------------|------------|
|                       | Labor                              | Nonlabor       | Labor                                                                                           | Nonlabor   | Labor                                                                                               | Nonlabor   |
| National <sup>1</sup> | Not Applicable                     | Not Applicable | \$4,320.08                                                                                      | \$2,647.79 | \$4,218.83                                                                                          | \$2,585.73 |

<sup>1</sup> For FY 2027, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

**TABLE 1D.— PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2027 PROPOSED RULE**

|          | Rate     |
|----------|----------|
| National | \$545.22 |

**TABLE 1E.— PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE—FY 2027 PROPOSED RULE**

|                       | Full Update<br>(2.4 Percent) | Reduced Update*<br>(0.4 Percent) |
|-----------------------|------------------------------|----------------------------------|
| Standard Federal Rate | \$52,177.04                  | \$51,157.95                      |

\* For LTCHs that fail to submit quality reporting data for FY 2027 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

#### BILLING CODE 4120–01–C

### Appendix A: Economic Analyses

#### I. Regulatory Impact Analysis

##### A. Statement of Need

This proposed rule is necessary to make payment and policy changes under the IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also, as we note later in this Appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule, such as the proposed updates to the IPPS and LTCH

PPS rates, and the proposals and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

##### 1. Acute Care Hospital Inpatient Prospective Payment System (IPPS) a. Proposed Update to the IPPS Payment Rates

In accordance with section 1886(b)(3)(B) of the Act and as described in section VI.B. of the preamble of this proposed rule, we are proposing to update the national standardized amount for inpatient hospital operating costs by the applicable percentage increase of 2.4 percent (that is, a proposed 3.2 percent market basket percentage increase with a proposed reduction of 0.8 percentage

point for the productivity adjustment). We are also proposing to update the hospital-specific rates by the applicable percentage increase (including the market basket percentage increase and the productivity adjustment).

Subsection (d) hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive a proposed applicable percentage increase of 1.6 percent, which reflects a one-quarter percent reduction of the market basket update for failure to submit quality data. Hospitals that are not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of zero percent, which reflects a three-quarter percent reduction of the market basket update for not meeting the requirements to be a meaningful EHR user.

Hospitals that are not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of -0.8 percent, which reflects a one-quarter

percent reduction of the market basket update for failure to submit quality data and a three-quarter percent reduction of the market basket update for not meeting the requirements to be a meaningful EHR user.

**b. Proposed Changes for the Add-On Payments for New Services and Technologies**

Consistent with sections 1886(d)(5)(K) and (L) of the Act, we review applications for new technology add-on payments based on the eligibility criteria at 42 CFR 412.87. As set forth in 42 CFR 412.87(f)(1), we consider whether a technology meets the criteria for the new technology add-on payment and announce the results as part of the annual updates and changes to the IPPS. New technology add-on payments are not budget neutral.

As discussed in section II.E.7. of the preamble of this proposed rule, we are proposing that for all applications received for new technology add-on payments for FY 2028 and subsequent fiscal years, including applications for FDA-designated Breakthrough Devices and QIDPs, or drugs approved under FDA's LPAD pathway, we would evaluate whether the technology is new and not substantially similar to an existing technology, and the technology must demonstrate that it meets the requirements under § 412.87(b) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. We note that this proposal, if finalized, would be effective beginning with new technology add-on payments for FY 2028, and there would be no impact of this proposal in FY 2027. In addition, we are proposing that all applications received for OPPS device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the CY 2028 OPPS application cycle ending on March 1, 2027, and subsequent calendar years would have to demonstrate that the technology meets the requirements currently reflected at § 419.66(c)(2)(i).

If all of the future Breakthrough Devices, QIDPs, and LPADs that would have applied for new technology add-on payments would have been approved under the criteria at § 412.87(b), this proposal has no impact relative to current policy. To the extent that there are future Breakthrough Devices, QIDPs, and LPADs that are the subject of applications for new technology add-on payments, and those applications would have been approved under the current new technology add-on payment

alternative pathway criteria, but would not meet the requirement to be new and not substantially similar to existing technologies and the requirements under § 412.87(b), this proposal would result in additional savings, but the savings are not estimable.

For future Breakthrough Devices that would have applied for OPPS device pass-through payment and would have met the criteria currently at § 419.66(c)(2)(i), this proposal has no impact relative to current policy. To the extent that there are future Breakthrough Devices that are the subject of applications for OPPS device pass-through payment, and those applications would have been approved under the current OPPS device pass-through payment alternative pathway criteria, but would not meet the requirements currently under § 419.66(c)(2)(i), this proposal would result in additional savings, but the savings are not estimable.

**c. Proposed Continued Transition for the Discontinuation of the Low Wage Index Hospital Policy**

In the FY 2025 interim final action with comment period (IFC) (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. For FY 2026 and subsequent fiscal years, consistent with the FY 2025 IFC, after considering the D.C. Circuit's decision in *Bridgeport Hospital v. Becerra*, we discontinued the low wage index hospital policy and the application of the low wage index budget neutrality factor to the standardized amounts (90 FR 36854).

For FY 2025 and FY 2026, consistent with our past practice to establish temporary transition policies to mitigate short-term instability and payment fluctuations, we established transition policies for hospitals significantly impacted by the discontinuation of the low wage index hospital policy using our authority under section 1886(d)(5)(I) of the Act. The transitional payment exception for FY 2025 for those hospitals was equal to the additional FY 2025 amount a hospital would have been paid under the IPPS if its FY 2025 wage index were equal to 95 percent of its FY 2024 wage index. The transitional payment exception for FY 2026 was equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024

wage index.<sup>566</sup> For FY 2025, we opted not to budget neutralize the interim transition policy given the timing of the *Bridgeport Hospital v. Becerra* decision. However, for FY 2026, we finalized a payment transition with a budget neutrality adjustment through notice-and-comment rulemaking for hospitals facing significant reductions over two years that would not be sufficiently mitigated by the wage index cap policy at 42 CFR 412.64(h)(7). We refer readers to the FY 2025 IFC (89 FR 80405 through 80421) and to the FY 2026 IPPS/LTCH PPS Final Rule (90 FR 36855 through 36857) for a full discussion of these transitional payment policies.

Some hospitals that previously benefitted from the low wage index hospital policy would continue to experience decreases of approximately 5 percent or more per year from their FY 2024 wage index (with the low wage index hospital policy applied). Therefore, we are proposing to extend the transitional exception to the calculation payments for FY 2027 and subsequent years for these hospitals in the same manner as we did for the FY 2026 wage index. In section III.F.6. of the preamble to this proposed rule, for FY 2027 we are proposing to use our authority under section 1886(d)(5)(I)(i) of the Act twice. First, we are proposing to adopt a narrow transitional exception to the calculation of FY 2027 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. Second, we are proposing to exercise our authority again to do so in a budget neutral manner.

**d. Additional Payment for Uncompensated Care to Medicare Disproportionate Share Hospitals (DSHs) and Supplemental Payment**

In this proposed rule, as required by section 1886(r)(2) of the Act, we are updating our estimates of the 3 factors used to determine uncompensated care payments for FY 2027. Beginning with FY 2023 (87 FR 49036 through 49038), we adopted a multiyear averaging methodology to determine Factor 3 of the uncompensated care payment methodology, which helps mitigate any large fluctuations in uncompensated care payments from year to year. Under this methodology, for FY 2025 and subsequent fiscal years, we determine Factor 3 for all eligible hospitals using a 3-year average of the data on

<sup>566</sup> 90.25 percent = 95 percent for FY 2025 \* 95 percent for FY 2026. This can also be expressed as .95^2.



uncompensated care costs from Worksheet S–10 for the 3 most recent fiscal years for which audited data are available. We propose to use a 3-year average of audited data on uncompensated care costs from Worksheet S–10, from the FY 2021, FY 2022, and FY 2023 cost reports, to calculate Factor 3 for FY 2027 for all eligible hospitals.

Beginning with FY 2023 (87 FR 49047 through 49051), we also established a supplemental payment for IHS and Tribal hospitals and hospitals located in Puerto Rico. In section IV.D. of the preamble of this proposed rule, we summarize the ongoing methodology for supplemental payments.

#### e. Rural Community Hospital Demonstration Program

We note, in section V.N. of the preamble of this proposed rule, we discuss the Rural Community Hospital (RCH) demonstration program. In past years, we made an adjustment to ensure the effects of the RCH demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. As discussed in that section, as we are not yet able to finalize the FY 2027 estimated costs of the demonstration at this time, we are not proposing to apply a budget neutrality offset in this FY 2027 IPPS/LTCH PPS proposed rule. Rather, we are proposing to apply budget neutrality offsets for both FY 2027 and FY 2028 to the national IPPS rates in the FY 2028 IPPS/LTCH PPS rulemaking. We would also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration. We refer the reader to section VI.N. of the preamble of this proposed rule for complete details on this proposal.

#### 2. Frontier Community Health Integration Project (FCHIP) Demonstration

The Frontier Community Health Integration Project (FCHIP) demonstration was authorized under section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act of 2010 (Pub. L. 114–158), and most recently reauthorized and extended by the Consolidated Appropriations Act of 2021 (Pub. L. 116–260). The legislation authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care in order to improve access to and better integrate the delivery of acute care, extended care and other

health care services to Medicare beneficiaries in certain rural areas. The FCHIP demonstration initial period was conducted in 10 critical access hospitals (CAHs) from August 1, 2016, to July 31, 2019, and the demonstration “extension period” began on January 1, 2022, to run through June 30, 2027.

The authorizing legislation requires the FCHIP demonstration to be budget neutral. In this proposed rule, we proposed to continue with the budget neutrality approach used in the demonstration initial period for the demonstration extension period—to offset payments across CAHs nationally—should the demonstration incur costs to Medicare.

#### 3. Proposed Update to the LTCH PPS Payment Rates

The proposed update to the LTCH PPS standard Federal payment rate for FY 2027 is discussed in section IX.C. of the preamble of this proposed rule. For FY 2027, we are proposing to establish an annual market basket update to the LTCH PPS standard Federal payment rate of 2.4 percent (that is, the 3.2 percent proposed market basket increase with a proposed reduction of 0.8 percentage point for the productivity adjustment, as required by section 1886(m)(3)(A)(i) of the Act). LTCHs that failed to submit quality data, as required by 1886(m)(5)(A)(i) of the Act would receive a proposed update of 0.4 percent for FY 2027, which reflects a 2.0 percentage point reduction for failure to submit quality data.

#### 4. Hospital Quality Programs

Section 1886(b)(3)(B)(viii) of the Act requires subsection (d) hospitals to report data in accordance with the requirements of the Hospital Inpatient Quality Reporting Program for purposes of measuring and making publicly available information on health care quality and links the quality data submission to the annual applicable percentage increase. Sections 1886(b)(3)(B)(ix), 1886(n), and 1814(l) of the Act require eligible hospitals and CAHs to demonstrate they are meaningful users of certified EHR technology for purposes of electronic exchange of health information to improve the quality of health care and link the submission of information demonstrating meaningful use to the annual applicable percentage increase for eligible hospitals and the applicable percent for CAHs. Section 1886(m)(5) of the Act requires each LTCH to submit quality measure data in accordance with the requirements of the Long Term Care Hospital Quality Reporting Program for purposes of measuring and making

publicly available information on health care quality, and to avoid a 2-percentage point reduction. Section 1886(o) of the Act requires the Secretary to establish a value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards established on an announced set of quality and efficiency measures for the fiscal year. The purposes of the Hospital Value-based Purchasing Program include measuring the quality of hospital inpatient care, linking hospital measure performance to payment, and making publicly available information on hospital quality of care. Section 1886(p) of the Act requires a reduction in payment for subsection (d) hospitals that rank in the worst-performing 25 percent with respect to measures of hospital-acquired conditions under the Hospital Acquired Condition Reduction Program for the purpose of measuring HACs, linking measure performance to payment, and making publicly available information on health care quality. Section 1886(q) of the Act requires a reduction in payment for subsection (d) hospitals for excess readmissions based on measures for applicable conditions under the Hospital Readmissions Reduction Program for the purpose of measuring readmissions, linking measure performance to payment, and making publicly available information on health care quality. Section 1886(k) of the Act applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as “PPS-exempt cancer hospitals” or “PCHs”) and requires PCHs to report data in accordance with the requirements of the PCH Quality Reporting Program for purposes of measuring and making publicly available information on the quality of care furnished by PCHs. However, there is no reduction in payment to a PCH that does not report data.

#### 5. Other Provisions

##### a. Transforming Episode Accountability Model (TEAM)

In section X.A. of the preamble of this proposed rule, we discuss the alternative payment model called the Transforming Episode Accountability Model (TEAM), which will be tested under the authority at section 1115A of the Act. Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and CHIP beneficiaries while reducing program expenditures. The underlying issue addressed by TEAM is that under the traditional fee-for-service (FFS)



payment system, Medicare makes separate payments to providers and suppliers for items and services furnished to a beneficiary over the course of an episode of care. Because providers and suppliers are paid for each individual item or service delivered, this may lead to care that is fragmented, unnecessary or duplicative, while making it challenging to invest in quality improvement or care coordination that would maximize patient benefit. We anticipate TEAM may reduce costs while maintaining or improving quality of care by bundling payment for items and services for a given episode and holding TEAM participants accountable for spending and quality performance, as well as by providing incentives to promote high quality and efficient care. Further, testing TEAM would allow us to learn more about the patterns of potentially inefficient utilization of health care services, as well as how to improve the beneficiary care experience during care transitions and incentivize quality improvements for common surgical episodes. This information could inform future Medicare payment policy and potentially establish the framework for managing clinical episodes as a standard practice in Original Medicare.

TEAM was finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) and subsequent updates were made in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536)). The proposals within this proposed rule address policy gaps and make technical or conforming updates to ensure TEAM has sound and well developed technical, administrative, and operational policies. We are also soliciting public comment on two RFIs that may inform future TEAM policy. Any future TEAM policy would go through notice and comment rulemaking.

#### b. Comprehensive Care for Joint Replacement Expanded (CJR–X) Model

In section X.C of the preamble of this proposed rule, we are proposing the expansion of the Comprehensive Care for Joint Replacement (CJR) model, with the expanded model referred to as CJR–X. Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and CHIP beneficiaries while reducing program expenditures. CJR–X participants would be accountable for the cost and quality of care for beneficiaries who receive a LEJR episode of care at their hospital. By holding CJR–X participants accountable, we anticipate this proposed model would reduce costs

while maintaining or improving quality of care, as well as by providing incentives to promote high quality and efficient care.

Based on our analysis, the CJR–X model will build upon the successful test of the CJR model and incorporate features from other CMS Innovation Center episode-based payment models such as the BPCI Advanced Model and TEAM. Given the strength of evidence from the CJR Model test, we believe its expansion across all eligible acute care hospitals is the logical follow on to continue driving value-based care for Medicare beneficiaries. Further, we believe CJR–X establishes a solid framework for managing clinical episodes as a standard practice in Original Medicare and could be used to inform episodes of care for Medicare Advantage or other payers.

Under the proposed CJR–X model, acute care hospitals paid under the IPPS and OPSS, with limited exclusions, would be accountable form LEJR episodes of care. We believe the model may benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode. The model would also provide financial incentives for providers to coordinate their efforts to meet patient needs and prevent future costs. CJR–X may benefit beneficiaries by holding hospitals accountable for the quality and cost of care for during the anchor hospitalization or anchor procedure and for 90 days after a beneficiary is discharged from the anchor hospitalization or anchor procedure, which could promote high quality and efficient service delivery that focuses on patient-centered care.

#### c. Provisions Regarding Acquisition Costs, Reasonable Costs, and Other Cost-Related Policies

In section X.D. of the preamble of this proposed rule, we are proposing to make payment and policy changes to ensure that Medicare reimburses non-renal organ acquisition costs to IOPOs and HCLs on a reasonable cost basis, in accordance with sections 1881(b)(2)(A) and 1861(v) of the Act. This proposed rule is also necessary to clarify, revise, and/or codify for all providers Medicare's reasonable cost payment policies related to allowable costs, and clarify and codify for all providers Medicare's policies related to overhead allocation. These three proposals are

needed to increase compliance with reasonable cost principles, increase payment accuracy, and increase provider understanding of reasonable cost principles. Additionally, this proposed rule is necessary to make a technical change to IOPO and HCL appeals policy, by codifying requirements that provide more consistency in the appeals process. Finally, this proposed rule is necessary to make technical corrections to clarify or correct regulation text.

The proposed changes in this proposed rule reflect our commitment to increasing payment accuracy for providers paid under reasonable cost principles, assisting providers in understanding reasonable cost principles, assisting IOPOs and HCLs in understanding their appeal rights, and responsibly stewarding the Medicare Trust Fund.

#### B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, "Regulatory Planning and Review"; Executive Order 13132, "Federalism"; Executive Order 13563, "Improving Regulation and Regulatory Review"; Executive Order 14192, "Unleashing Prosperity Through Deregulation"; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1). We have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these regulations, and the Departments have provided the following assessment of their impact.

We estimate that the proposed changes for FY 2027 acute care hospital operating and capital payments will redistribute amounts in excess of \$100 million to acute care hospitals. The proposed applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated \$1.9 billion increase in payments in FY 2027, primarily driven by the net effect of changes in FY 2027 operating payments, including uncompensated care payments, FY 2027 capital payments, the expiration of the temporary changes in the low-volume hospital program, the expiration of the MDH program, and new technology add-on payment changes. These changes are relative to payments made in FY 2026. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments of approximately \$55 million in FY 2027 relative to FY 2026.

Our operating payment impact estimate includes the 2.4 percent applicable percentage increase to the standardized amount (reflecting the proposed 3.2 percent market basket rate-of-increase reduced by the proposed 0.8 percentage point productivity adjustment). The estimates of IPPS operating payments to acute care hospitals generally do not reflect any changes in hospital admissions or real case-mix intensity, which would also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule will affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866,

the Office of Management and Budget has reviewed this proposed rule.

### *C. Objectives of the IPPS and the LTCH PPS*

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this proposed rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this proposed rule contains a range of policies, we refer readers to the section of the proposed rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the proposed policy.

### *D. Limitations of Our Analysis*

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2027, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally, unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific proposed policies in the discussion of those policies as needed.

### *E. Hospitals Included In and Excluded From the IPPS*

The prospective payment systems for hospital inpatient operating and capital related-costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 26 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special

characteristics of the prospective payment methodology for these hospitals. Among other short term, acute care hospitals, hospitals in Maryland are paid in accordance with the AHEAD Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2026, there were 3,013 IPPS acute care hospitals included in our analysis. This represents approximately 51 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,385 CAHs. These small, limited-service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, cancer hospitals, extended neoplastic disease care hospital, and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and policy changes to the LTCH PPS for FY 2027 is discussed in section I.J. of this Appendix.

### *F. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs and Medicare DSH Uncompensated Care Payments*

#### *1. Basis and Methodology of Estimates*

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2027 for operating costs of acute care hospitals and for uncompensated care payments. The proposed FY 2027 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix. A more detailed analysis of the proposed update to uncompensated care payments is discussed in section I.G.2 of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2027 operating

payments including uncompensated care payments will increase by 1.2 percent compared to FY 2026. The operating payment impacts generally do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes on the operating and capital prospective payment systems. This section primarily deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the best available claims data to enable us to estimate the impacts on payments per case of certain proposed changes in this proposed rule. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in operating payments per case presented in this section are taken from the FY 2025 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the best available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not generally adjust for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2025 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of proposed payments under the capital IPPS, and the impact of proposed payments other than inpatient operating payments

including uncompensated care payments are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2027 are discussed in section I.I. of this Appendix.

We discuss the following proposed changes:

- The estimated effects of outlier payments returning to their targeted levels in FY 2027 as compared to the estimated outlier payments for FY 2026 produced from our payment simulation model.

- The effects of the application of the proposed applicable percentage increase of 2.4 percent (that is, a proposed 3.2 percent market basket rate-of-increase with a reduction of 0.8 percentage point for the proposed productivity adjustment), and the proposed applicable percentage increase (including the proposed market basket rate-of-increase and the proposed productivity adjustment) to the hospital-specific rates.

- The effects of the proposed changes to estimated uncompensated care payments in FY 2027 as compared to FY 2026.

- The effects of the expiration of the special payment status for MDHs beginning January 1, 2027 under current law.

- The effects of the proposed changes to the relative weights and MS-DRG Grouper.

- The effects of the proposed changes in hospitals' wage index values due to the effects of the proposed incorporation of updated wage data from hospitals' cost reporting periods and the proposed changes in wage index reclassifications.

- The total estimated change in payments based on the proposed FY 2027 policies relative to payments based on FY 2026 policies.

To illustrate the impact of the proposed FY 2027 changes, our analysis begins with a FY 2026 baseline simulation model using: the FY 2026 national adjusted operating standardized amount; the FY 2026 MS-DRG Grouper (Version 43); the FY 2026 CSHA designations for hospitals based on the OMB definitions from the 2020 Census; the FY 2026 wage index, including the FY 2026 labor and nonlabor share percentages; FY 2026 uncompensated care payments; and FY 2026 outlier payments which reflects our estimate of 6.0 percent of total operating MS-DRG and outlier payments as produced by our payment simulation model based on FY 2025 MedPAR data.

Our comparison illustrates the proposed percent change in payments per case from FY 2026 to FY 2027. The

update to the standardized amount is a significant factor in the percent change in payments per case. In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the "applicable percentage increase." For FY 2027, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four proposed possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section VI.B. of the preamble of this proposed rule for a complete discussion of the FY 2027 inpatient hospital update, including the four proposed possible applicable percentage increases. For purposes of the simulations shown later in this section, we modeled the proposed payment changes for FY 2027 using a reduced update for hospitals that (1) failed to submit quality data but are meaningful EHR users; (2) are identified as not meaningful EHR users that do submit quality data; and (3) are identified as not meaningful EHR users that do not submit quality data. The reduced updates used for these hospitals are discussed previously and in section VI.B. of the preamble of this proposed rule and these hospitals are identified in the impact file posted in conjunction with this proposed rule.

We note, section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act for hospitals that fail to submit quality data or are not a meaningful EHR users. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs for FY 2027 are the same as the four proposed applicable percentage increases discussed in section VI.B. of the preamble of this proposed rule.

## 2. Impact Analysis of Proposed Changes on Payments for IPPS Operating Costs and Uncompensated Care Payments

Table I displays the results of our analysis of the proposed changes for FY 2027 on payments for IPPS operating costs and uncompensated care payments. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the acute care hospitals included in the analysis.

The next two rows of Table I contain hospitals categorized according to their geographic location: urban and rural. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2027 payment classifications, including any reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act.

For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under section 1886(d)(8)(B) of the Act, also known as Lugar hospitals, and section 1886(d)(8)(E) of the Act as implemented at 42 CFR 412.103).

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH payment purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next six rows examine the impacts of the changes on rural

hospitals by special payment groups (SCHs and MDHs) and reclassification status from urban to rural in accordance with section 1886(d)(8)(E) of the Act.

The next series of groupings are based on the type of ownership and the hospital's Medicare and Medicaid utilization expressed as a percent of total inpatient days. These data were taken from the most recent available Medicare cost reports.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2027 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act as implemented at 42 CFR 412.103. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act, also known as Lugar hospitals.

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**TABLE 1.—IMPACT ANALYSIS OF PROPOSED CHANGES ON PAYMENTS FOR IPPS  
OPERATING COSTS AND UNCOMPENSATED CARE PAYMENTS FOR FY 2027**

|                                   | Number of Hospitals <sup>1</sup> | Proposed FY 2027 Outlier Payments (1) <sup>2</sup> | Proposed FY 2027 Hospital Rate Update (2) <sup>3</sup> | MDH Expiration (3) <sup>4</sup> | Proposed FY 2027 Uncompensated Care Payments (4) <sup>5</sup> | Proposed FY 2027 Weights and DRG Changes with Application of Recalibration Budget Neutrality (5) <sup>6</sup> | Proposed FY 2027 Wage Index (6) <sup>7</sup> | All Proposed FY 2027 Changes (7) <sup>8</sup> |
|-----------------------------------|----------------------------------|----------------------------------------------------|--------------------------------------------------------|---------------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------------------------------|
| <b>All Hospitals</b>              | 3,013                            | -0.7                                               | 2.2                                                    | -0.1                            | -0.2                                                          | 0.0                                                                                                           | -0.1                                         | 1.2                                           |
| <b>By Geographic Location:</b>    |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| Urban hospitals                   | 2,357                            | -0.7                                               | 2.2                                                    | -0.1                            | -0.2                                                          | 0.0                                                                                                           | -0.1                                         | 1.2                                           |
| Rural hospitals                   | 656                              | -0.3                                               | 2.3                                                    | -0.4                            | -0.5                                                          | -0.5                                                                                                          | 0.3                                          | 0.8                                           |
| <b>Bed Size (Urban):</b>          |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| 0-99 beds                         | 639                              | -0.5                                               | 2.3                                                    | -1.4                            | -0.3                                                          | 0.0                                                                                                           | 0.0                                          | 0.0                                           |
| 100-199 beds                      | 673                              | -0.6                                               | 2.3                                                    | -0.1                            | -0.2                                                          | -0.3                                                                                                          | -0.1                                         | 1.0                                           |
| 200-299 beds                      | 401                              | -0.6                                               | 2.3                                                    | 0.0                             | -0.3                                                          | -0.2                                                                                                          | -0.3                                         | 1.0                                           |
| 300-499 beds                      | 391                              | -0.7                                               | 2.3                                                    | 0.0                             | -0.2                                                          | 0.0                                                                                                           | -0.1                                         | 1.3                                           |
| 500 or more beds                  | 251                              | -0.8                                               | 2.2                                                    | 0.0                             | -0.1                                                          | 0.2                                                                                                           | 0.0                                          | 1.6                                           |
| <b>Bed Size (Rural):</b>          |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| 0-49 beds                         | 316                              | -0.2                                               | 2.2                                                    | -0.9                            | -1.1                                                          | -0.7                                                                                                          | 0.2                                          | -0.7                                          |
| 50-99 beds                        | 175                              | -0.2                                               | 2.3                                                    | -1.2                            | -0.4                                                          | -0.6                                                                                                          | -0.1                                         | -0.3                                          |
| 100-149 beds                      | 95                               | -0.2                                               | 2.3                                                    | 0.0                             | -0.4                                                          | -0.6                                                                                                          | 0.1                                          | 1.1                                           |
| 150-199 beds                      | 41                               | -0.3                                               | 2.3                                                    | 0.0                             | -0.7                                                          | -0.4                                                                                                          | 0.1                                          | 1.1                                           |
| 200 or more beds                  | 29                               | -0.5                                               | 2.3                                                    | 0.0                             | -0.3                                                          | -0.1                                                                                                          | 1.1                                          | 2.5                                           |
| <b>Urban by Region:</b>           |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| New England                       | 102                              | -0.7                                               | 2.3                                                    | -0.1                            | -0.1                                                          | -0.1                                                                                                          | 1.9                                          | 3.3                                           |
| Middle Atlantic                   | 272                              | -0.7                                               | 2.3                                                    | -0.1                            | 0.0                                                           | -0.1                                                                                                          | -0.3                                         | 1.1                                           |
| East North Central                | 364                              | -0.5                                               | 2.3                                                    | -0.2                            | -0.3                                                          | 0.0                                                                                                           | -0.9                                         | 0.4                                           |
| West North Central                | 155                              | -0.6                                               | 2.3                                                    | 0.0                             | -0.4                                                          | 0.1                                                                                                           | 0.4                                          | 1.8                                           |
| South Atlantic                    | 393                              | -0.6                                               | 2.2                                                    | -0.1                            | -0.3                                                          | 0.0                                                                                                           | -0.2                                         | 1.1                                           |
| East South Central                | 140                              | -0.8                                               | 2.2                                                    | 0.0                             | -0.3                                                          | 0.1                                                                                                           | 0.6                                          | 1.8                                           |
| West South Central                | 357                              | -0.5                                               | 2.1                                                    | 0.0                             | -0.2                                                          | 0.1                                                                                                           | -0.8                                         | 0.7                                           |
| Mountain Pacific                  | 177                              | -0.6                                               | 2.3                                                    | 0.0                             | 0.1                                                           | 0.2                                                                                                           | -1.0                                         | 1.0                                           |
| Pacific                           | 346                              | -1.1                                               | 2.3                                                    | 0.0                             | -0.2                                                          | 0.0                                                                                                           | 0.4                                          | 1.5                                           |
| <b>Rural by Region:</b>           |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| New England                       | 19                               | -0.6                                               | 2.3                                                    | -1.0                            | -0.3                                                          | -0.3                                                                                                          | 2.4                                          | 2.4                                           |
| Middle Atlantic                   | 47                               | -0.4                                               | 2.3                                                    | -0.1                            | -0.1                                                          | -0.6                                                                                                          | 0.0                                          | 1.2                                           |
| East North Central                | 106                              | -0.3                                               | 2.3                                                    | -1.2                            | -0.4                                                          | -0.5                                                                                                          | -0.3                                         | -0.4                                          |
| West North Central                | 72                               | -0.2                                               | 2.3                                                    | -0.3                            | -0.5                                                          | -0.4                                                                                                          | -0.1                                         | 0.9                                           |
| South Atlantic                    | 109                              | -0.3                                               | 2.2                                                    | -0.5                            | -0.9                                                          | -0.6                                                                                                          | 0.8                                          | 0.7                                           |
| East South Central                | 122                              | -0.2                                               | 2.2                                                    | -0.3                            | -0.7                                                          | -0.5                                                                                                          | 0.4                                          | 0.9                                           |
| West South Central                | 117                              | -0.2                                               | 2.1                                                    | -0.1                            | -0.5                                                          | -0.5                                                                                                          | -0.5                                         | 0.0                                           |
| Mountain Pacific                  | 40                               | -0.2                                               | 2.3                                                    | 0.0                             | -0.6                                                          | -0.2                                                                                                          | 0.0                                          | 1.5                                           |
| Puerto Rico                       | 24                               | -0.2                                               | 2.4                                                    | 0.0                             | 0.0                                                           | -0.8                                                                                                          | 0.2                                          | 1.5                                           |
| <b>Puerto Rico Hospitals</b>      |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| Puerto Rico Hospitals             | 51                               | -0.3                                               | 1.5                                                    | 0.0                             | -2.1                                                          | -0.2                                                                                                          | -0.9                                         | -2.0                                          |
| <b>By Payment Classification:</b> |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| Urban hospitals                   | 1,528                            | -0.7                                               | 2.2                                                    | 0.0                             | -0.2                                                          | -0.1                                                                                                          | 0.1                                          | 1.3                                           |
| Rural areas                       | 1,485                            | -0.7                                               | 2.2                                                    | -0.1                            | -0.2                                                          | 0.1                                                                                                           | -0.2                                         | 1.2                                           |
| <b>Teaching Status:</b>           |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| Non-teaching                      | 1,710                            | -0.6                                               | 2.3                                                    | -0.3                            | -0.3                                                          | -0.2                                                                                                          | 0.0                                          | 1.0                                           |
| Fewer than 100 residents          | 997                              | -0.6                                               | 2.3                                                    | -0.1                            | -0.2                                                          | -0.1                                                                                                          | -0.2                                         | 1.1                                           |
| 100 or more residents             | 306                              | -0.8                                               | 2.2                                                    | 0.0                             | -0.1                                                          | 0.2                                                                                                           | 0.0                                          | 1.5                                           |

|                                                                                                                               | Number of Hospitals <sup>1</sup> | Proposed FY 2027 Outlier Payments (1) <sup>2</sup> | Proposed FY 2027 Hospital Rate Update (2) <sup>3</sup> | MDH Expiration (3) <sup>4</sup> | Proposed FY 2027 Uncompensated Care Payments (4) <sup>5</sup> | Proposed FY 2027 Weights and DRG Changes with Application of Recalibration Budget Neutrality (5) <sup>6</sup> | Proposed FY 2027 Wage Index (6) <sup>7</sup> | All Proposed FY 2027 Changes (7) <sup>8</sup> |
|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------------------------------------|--------------------------------------------------------|---------------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------------------------------|
| <b>Urban DSH:</b>                                                                                                             |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| Non-DSH                                                                                                                       | 355                              | -0.7                                               | 2.4                                                    | -0.1                            | 0.0                                                           | 0.2                                                                                                           | -0.2                                         | 1.7                                           |
| 100 or more beds                                                                                                              | 837                              | -0.7                                               | 2.2                                                    | 0.0                             | -0.2                                                          | -0.1                                                                                                          | 0.1                                          | 1.3                                           |
| Less than 100 beds                                                                                                            | 336                              | -0.5                                               | 2.2                                                    | -0.1                            | -0.7                                                          | -0.5                                                                                                          | 0.0                                          | 0.4                                           |
| <b>Rural DSH:</b>                                                                                                             |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| Non-DSH                                                                                                                       | 114                              | -0.7                                               | 2.4                                                    | -1.2                            | 0.0                                                           | 0.1                                                                                                           | 0.0                                          | 0.6                                           |
| SCH                                                                                                                           | 222                              | -0.1                                               | 2.3                                                    | 0.0                             | -0.3                                                          | -0.6                                                                                                          | -0.1                                         | 1.2                                           |
| RRC                                                                                                                           | 920                              | -0.7                                               | 2.2                                                    | 0.0                             | -0.2                                                          | 0.1                                                                                                           | -0.2                                         | 1.2                                           |
| 100 or more beds                                                                                                              | 41                               | -0.6                                               | 2.2                                                    | -0.1                            | -0.2                                                          | 0.0                                                                                                           | -0.1                                         | 1.3                                           |
| Less than 100 beds                                                                                                            | 188                              | -0.3                                               | 2.2                                                    | -2.6                            | -0.9                                                          | -0.7                                                                                                          | 0.3                                          | -2.2                                          |
| <b>Urban teaching and DSH:</b>                                                                                                |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| Both teaching and DSH                                                                                                         | 483                              | -0.7                                               | 2.2                                                    | 0.0                             | -0.1                                                          | -0.1                                                                                                          | 0.1                                          | 1.4                                           |
| Teaching and no DSH                                                                                                           | 62                               | -0.6                                               | 2.4                                                    | -0.2                            | 0.0                                                           | -0.1                                                                                                          | -0.1                                         | 1.4                                           |
| No teaching and DSH                                                                                                           | 690                              | -0.7                                               | 2.2                                                    | 0.0                             | -0.3                                                          | -0.2                                                                                                          | 0.0                                          | 1.0                                           |
| No teaching and no DSH                                                                                                        | 293                              | -0.7                                               | 2.4                                                    | 0.0                             | 0.0                                                           | 0.3                                                                                                           | -0.2                                         | 1.9                                           |
| <b>Special Hospital Types:</b>                                                                                                |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| SCH                                                                                                                           | 425                              | -0.2                                               | 2.3                                                    | 0.0                             | -0.2                                                          | -0.3                                                                                                          | 0.2                                          | 1.9                                           |
| MDH                                                                                                                           | 160                              | -0.2                                               | 2.3                                                    | -8.6                            | -0.5                                                          | -0.5                                                                                                          | 0.1                                          | -7.6                                          |
| <b>Type of Ownership:</b>                                                                                                     |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| Voluntary                                                                                                                     | 1,909                            | -0.7                                               | 2.3                                                    | -0.1                            | -0.2                                                          | 0.0                                                                                                           | 0.0                                          | 1.2                                           |
| Proprietary                                                                                                                   | 693                              | -0.5                                               | 2.3                                                    | 0.0                             | -0.3                                                          | 0.0                                                                                                           | -0.5                                         | 1.0                                           |
| Government                                                                                                                    | 409                              | -0.8                                               | 2.1                                                    | 0.0                             | -0.2                                                          | 0.1                                                                                                           | 0.1                                          | 1.3                                           |
| <b>Medicare Utilization as a Percent of Inpatient Days:</b>                                                                   |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| 0-25                                                                                                                          | 1,666                            | -0.7                                               | 2.2                                                    | 0.0                             | -0.2                                                          | 0.0                                                                                                           | -0.1                                         | 1.2                                           |
| 25-50                                                                                                                         | 1,272                            | -0.7                                               | 2.3                                                    | -0.2                            | -0.2                                                          | -0.1                                                                                                          | 0.0                                          | 1.3                                           |
| 50-65                                                                                                                         | 42                               | -0.6                                               | 2.4                                                    | -0.1                            | -0.1                                                          | 0.0                                                                                                           | -0.4                                         | 1.2                                           |
| Over 65                                                                                                                       | 9                                | -0.3                                               | 2.4                                                    | -4.6                            | 0.0                                                           | 1.3                                                                                                           | 0.9                                          | -0.4                                          |
| <b>Medicaid Utilization as a Percent of Inpatient Days:</b>                                                                   |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| 0-25                                                                                                                          | 2,009                            | -0.6                                               | 2.3                                                    | -0.1                            | -0.2                                                          | 0.0                                                                                                           | 0.0                                          | 1.3                                           |
| 25-50                                                                                                                         | 886                              | -0.8                                               | 2.2                                                    | 0.0                             | -0.2                                                          | 0.1                                                                                                           | -0.3                                         | 1.1                                           |
| 50-65                                                                                                                         | 88                               | -0.7                                               | 1.8                                                    | 0.0                             | -0.1                                                          | -0.4                                                                                                          | 0.0                                          | 0.7                                           |
| Over 65                                                                                                                       | 30                               | -1.0                                               | 2.0                                                    | 0.0                             | 0.2                                                           | -0.5                                                                                                          | 0.1                                          | 0.9                                           |
| <b>FY 2027 Reclassifications:</b>                                                                                             |                                  |                                                    |                                                        |                                 |                                                               |                                                                                                               |                                              |                                               |
| All Reclassified Hospitals                                                                                                    | 1,195                            | -0.7                                               | 2.2                                                    | -0.1                            | -0.2                                                          | 0.1                                                                                                           | -0.1                                         | 1.3                                           |
| Non-Reclassified Hospitals                                                                                                    | 1,818                            | -0.7                                               | 2.3                                                    | -0.1                            | -0.2                                                          | -0.1                                                                                                          | -0.1                                         | 1.1                                           |
| Urban Hospitals Reclassified                                                                                                  | 1,007                            | -0.7                                               | 2.2                                                    | -0.1                            | -0.2                                                          | 0.1                                                                                                           | -0.1                                         | 1.3                                           |
| Urban Non-reclassified Hospitals                                                                                              | 1,368                            | -0.7                                               | 2.2                                                    | 0.0                             | -0.2                                                          | -0.1                                                                                                          | -0.1                                         | 1.1                                           |
| Rural Hospitals Reclassified Full Year                                                                                        | 276                              | -0.3                                               | 2.3                                                    | -0.2                            | -0.5                                                          | -0.5                                                                                                          | 0.2                                          | 1.0                                           |
| Rural Non-reclassified Hospitals Full Year                                                                                    | 362                              | -0.3                                               | 2.3                                                    | -0.6                            | -0.6                                                          | -0.5                                                                                                          | 0.4                                          | 0.6                                           |
| All hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103 | 882                              | -0.7                                               | 2.2                                                    | -0.1                            | -0.2                                                          | 0.1                                                                                                           | -0.2                                         | 1.2                                           |

|                                                                                     | Number of Hospitals <sup>1</sup> | Proposed FY 2027 Outlier Payments (1) <sup>2</sup> | Proposed FY 2027 Hospital Rate Update (2) <sup>3</sup> | MDH Expiration (3) <sup>4</sup> | Proposed FY 2027 Uncompensated Care Payments (4) <sup>5</sup> | Proposed FY 2027 Weights and DRG Changes with Application of Recalibration Budget Neutrality (5) <sup>6</sup> | Proposed FY 2027 Wage Index (6) <sup>7</sup> | All Proposed FY 2027 Changes (7) <sup>8</sup> |
|-------------------------------------------------------------------------------------|----------------------------------|----------------------------------------------------|--------------------------------------------------------|---------------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------------------------------|
| Other Reclassified Hospitals (Section 1886(d)(8)(B), also known as Lujan hospitals) | 53                               | -0.3                                               | 2.3                                                    | -1.8                            | -0.6                                                          | -0.7                                                                                                          | 0.5                                          | -0.5                                          |

<sup>1</sup> Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2025, and hospital cost report data are from the latest available reporting periods.

<sup>2</sup> This column displays the effects of estimated outlier payments returning to their targeted levels in FY 2027 as compared to the estimated outlier payments for FY 2026.

<sup>3</sup> This column displays the payment impact of the hospital rate update, including the 2.4 percent update to the national standardized amount and the hospital-specific rate (the 3.2 percent IPPS market basket rate-of-increase reduced by the 0.8 percentage point for the productivity adjustment).

<sup>4</sup> This column displays the impact of the expiration of the MDH status on January 1, 2027, a non-budget neutral payment provision.

<sup>5</sup> This column displays the effects of the proposed changes to estimated uncompensated care payments in FY 2027 as compared to FY 2026 as a percent change in estimated total payments. See also the table in section I.G.2 of this Appendix.

<sup>6</sup> This column displays the payment impact of proposed Version 44 Grouper, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2025 MedPAR data, and the 10-percent cap where the relative weight for a MS-DRG will decrease by more than ten percent in a given fiscal year. This column displays the application of the proposed recalibration budget neutrality factor and the 10-percent cap budget neutrality factor (which can be found in section II.A.4 of the Addendum of this proposed rule).

<sup>7</sup> This column displays the effects of the changes to the proposed FY 2027 wage index. This includes: (1) the proposed update to wage index data using FY 2023 cost report data, the application of the proposed wage index budget neutrality factor and the proposed update to the labor and nonlabor shares; (2) the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MCCRB), showing the payment impact of going from FY 2026 reclassifications to the reclassifications scheduled to be in effect for FY 2027; (3) the effects of the application of the proposed rural floor; (4) the effects of urban to rural reclassifications under section 1886(d)(8) of the Act on the proposed wage index; (5) the effects of the application of "LUGAR" status under section 1886(d)(10) of the Act on the proposed wage index; and (6) the proposed adjustments to the wage index driven by non-budget neutral policies. These non-budget neutral policies include: (a) the imputed floor for all-urban states; (b) the policy that requires hospitals located in frontier States have a wage index no less than 1.0; and (c) the policy which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. The budget neutrality factors for the effects that are budget neutral can be found in section II.A.4 of the Addendum of this proposed rule. This column also displays the redistributive effects of the budget neutral transition for the discontinuation of the low wage index hospital policy from hospitals that do not benefit from the transition to hospitals that do benefit (primarily all the hospitals located in Puerto Rico) due to the associated budget neutrality factor. The budget neutrality factor for the transition can be found in section II.A.4 of the Addendum of this final rule.

<sup>8</sup> This column shows the estimated change in proposed payments from FY 2026 to FY 2027.

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## a. Effects of the Outlier Adjustment (Column 1)

This column reflects the effect of estimated outlier payments returning to their targeted levels in FY 2027 as compared to the estimated outlier payments for FY 2026 produced from our payment simulation model. As discussed in section II.A.4.i. of the Addendum to this proposed rule, the statute requires that outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments, and also requires that the average standardized amount be reduced by a factor to account for the estimated proportion of total DRG payments made to outlier cases. We continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount, just as we did for FY 2026. Therefore, our proposed estimate of payments per discharge for FY 2027 from our payment simulation model reflects this 5.1 percent outlier payment target. Our payment simulation model shows that estimated outlier payments for FY 2026 were greater than that target by approximately 0.9 percentage points.

Overall, hospitals will experience a 0.7 percent decrease in payments primarily due to the estimated -0.9 percent change in outlier payments produced by our payment simulation model when returning to the 5.1 percent outlier target for FY 2027 in combination with interactive effects among the various add-on payment factors.

## b. Effects of the Proposed Hospital Update (Column 2)

As discussed in section VI.B. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 3.2 percent IPPS market basket rate-of-increase reduced by 0.8 percentage point for the proposed productivity adjustment. As a result, we are proposing to make a 2.4 percent update to the national standardized amount. This column also includes the proposed update to the hospital-specific rates which includes the proposed 3.2 percent market basket rate-of-increase reduced by 0.8 percentage point for the proposed productivity adjustment. As a result, we are proposing to make a 2.4 percent update to the hospital-specific rates. This column also includes any applicable adjustments for hospitals that fail to comply with the quality data

submission requirements and/or are not meaningful EHR users.

Overall, hospitals are expected to experience a 2.2 percent increase in payments primarily due to the combined effects of the proposed hospital update to the national standardized amount and the proposed hospital update to the hospital-specific rates.

## c. Effects of the Expiration of MDH Special Payment Status (Column 3)

Column 3 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision. Section 6202 of the Consolidated Appropriations Act, 2026 further extended the MDH program through December 31, 2026. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027. Hospitals that qualify to be MDHs receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate amount plus 75 percent of the difference between payments based on the Federal rate and payments based on the hospital-specific rate (a hospital-specific cost-based rate). Because this provision is not budget neutral, the expiration of this payment provision is estimated to result in a 0.1 percent decrease in IPPS payments overall. There are currently 160 MDHs, of which we estimate 80 would be paid under the blended payment of the Federal rate and hospital-specific rate if the MDH program were not set to expire. Because those 80 MDHs will no longer receive the blended payment and will be paid only under the Federal rate beginning January 1, 2027, it is estimated that those hospitals would experience an overall decrease in payments of approximately \$110 million (relative to the MDH program payments they received for FY 2026 discharges).

## d. Effects of the Proposed Changes in Uncompensated Care Payments (UCP) (Column 4)

Column 4 shows the effects of the proposed changes in uncompensated care payments for eligible hospitals in FY 2027. As discussed in section IV.E. of the preamble of this proposed rule, the total proposed uncompensated care payments and proposed supplemental payments equal approximately \$8.5 billion. Overall, hospitals would experience a 0.2 percent decrease in total operating IPPS payments relative to FY 2026 payments due to the proposed change in uncompensated care payments. For a more detailed impact analysis of the proposed changes

to uncompensated care payments, we refer readers to section I.G.2 of appendix A to this proposed rule.

## e. Effects of the Proposed Changes to the MS-DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 5)

Column 5 shows the effects of the proposed changes to the MS-DRGs and relative weights with the application of the proposed recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a proposed recalibration budget neutrality factor to account for the changes in MS-DRGs and relative weights to ensure that the overall payment impact is budget neutral. We also applied the permanent 10-percent cap on the reduction in a MS-DRG's relative weight in a given year and an associated recalibration cap budget neutrality factor to account for the 10-percent cap on relative weight reductions to ensure that the overall payment impact is budget neutral.

As discussed in section II.D. of the preamble of this proposed rule, for FY 2027, we calculated the proposed MS-DRG relative weights using the FY 2025 MedPAR data grouped to the proposed Version 44 (FY 2027) MS-DRGs. The proposed reclassification changes to the GROUPE are described in more detail in section II.C. of the preamble of this proposed rule.

The "All Hospitals" line in Column 5 indicates that changes due to the MS-DRGs and relative weights are expected to result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor (discussed in section II.A.4.a. of the Addendum to this proposed rule) and the recalibration cap budget neutrality factor to the standardized amount (discussed in section II.A.4.b. of the Addendum to this proposed rule).

## f. Effects of the Proposed Wage Index Changes (Column 6)

Column 6 shows the impact of the proposed changes to hospitals' FY 2027 wage index as compared to hospitals' FY 2026 wage index. Overall, the FY 2027 wage index changes are expected to lead to a 0.1 percent decrease for all hospitals, as shown in Column 6. This change is a result of the proposed updates to the wage data reported by hospitals, changes in the geographic



reclassifications of hospitals, and the interactions of those changes with statutory wage index floors and exceptions. We combine these changes because the complex and interactive ways in which hospitals increasingly seek to maximize their wage index values in a given year render isolation of these effects in a year-over-year context less informative. For example, the impact of the proposed updates to the wage data reported by hospitals in the absence of the changes in geographic reclassification and especially the interaction of both of those with statutory wage index floors and exceptions is less meaningful than showing the combined effect of those factors.

Specifically, this column in Table I shows the combined effects of the application of the following proposed FY 2027 wage index changes relative to FY 2026:

(1) Effects of the Proposed Changes to the Wage Data

Column 6 reflects the effects of the proposed updated wage data and the proposed labor and non-labor shares, with the application of the proposed wage index budget neutrality factor for FY 2027 relative to FY 2026.

Section 1886(d)(3)(E) of the Act requires that we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2027 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2022, and before October 1, 2023. Column 6 reflects the proposed percentage change in payments when going from a model using the FY 2026 wage index based on FY 2026 reclassifications and the FY 2026 labor-related share of 66.0 percent, to a model using the proposed FY 2027 wage index based on FY 2027 reclassifications (as described in further detail in the next section) and the proposed labor-related share of 66.0 percent, while holding other payment parameters, such as use of the proposed Version 44 MS-DRG GROUPER, constant.

In addition, the column incorporates the application of the proposed wage index budget neutrality to the national standardized amount. As discussed in section II.A.4.c. of the Addendum to this proposed rule, for FY 2027 we calculated the proposed wage index budget neutrality factor to ensure that payments under the proposed wage index calculated from the proposed updated wage data and the proposed labor-related share of 66.0 percent are

budget neutral, without regard to the lower share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. This proposed budget neutrality factor can be found in the summary table of the proposed FY 2027 budget neutrality factors in section II.A.4. of the Addendum to this proposed rule.

(2) Effects of MGCRB, Urban to Rural, and “Lugar” Reclassifications

Column 6 reflects the impact of MGCRB reclassification decisions under section 1886(d)(10) of the Act, urban to rural reclassifications under section 1886(d)(8)(E) of the Act, and Lugar status redesignations under section 1886(d)(8)(B) of the Act on the proposed wage index for FY 2027 relative to FY 2026. The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, as discussed in section II.A.4.d. of the Addendum to this proposed rule, we apply a proposed reclassification budget neutrality adjustment to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral. This proposed budget neutrality factor can be found in the summary table of the proposed FY 2027 budget neutrality factors in section II.A.4. of the Addendum to this proposed rule.

Table 2 listed in section VI. of the Addendum to this proposed rule and available on the CMS website reflects the reclassifications for FY 2027 at the time of development of this proposed rule. For further information on MGCRB reclassifications, urban to rural reclassifications and Lugar status redesignations, we refer readers to section III.E of the preamble of this proposed rule.

(3) The Effects of the Proposed Rural Floor, Including Proposed Budget Neutrality Adjustment

Column 6 reflects the effects of the application of the proposed rural floor and the application of the proposed rural floor budget neutrality on the proposed wage index for FY 2027 relative to FY 2026. As discussed in section III.F.1. of the preamble of this proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same state. We apply a uniform budget neutrality adjustment to the wage index as discussed in section II.A.4.e. of the Addendum to this proposed rule. All IPPS hospitals in our model have their

wage indexes reduced by the proposed rural floor budget neutrality adjustment. This proposed budget neutrality factor can be found in the summary table of the FY 2027 budget neutrality factors in section II.A.4. of the Addendum to this proposed rule.

(4) Effects the Application of the Proposed Imputed Floor, Proposed Frontier State Wage Index, and Proposed Out-Migration Adjustment

Lastly, this column also reflects the combined effects of the application of the following non-budget neutral provisions for FY 2027 relative to FY 2026: (a) the imputed floor under section 1886(d)(3)(E)(iv)(I) and (II) of the Act for certain all-urban States (as discussed in section III.F.2. of the preamble of this proposed rule); (b) the minimum post-reclassified wage index of 1.00 for all hospitals located in “frontier States” as required by section 1886(d)(3)(E)(iii) Act (as discussed in section III.F.3. of the preamble of this proposed rule); and (c) the effects of the proposed out-migration adjustment under section 1886(d)(13) of the Act (as discussed in section III.F.4. of the preamble of this proposed rule).

g. Effects of All Proposed FY 2027 Changes (Column 7)

Column 7 shows our estimate of the proposed changes in payments per discharge from FY 2026 and FY 2027, resulting from all proposed changes for FY 2027 included in Table I. It includes the combined effects of the year-over-year change of the factors described in the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 1.2 percent for FY 2027 relative to FY 2026, which is primarily driven by the proposed changes reflected in Column 1 (proposed outlier payments), Column 2 (proposed hospital update) and Column 4 (proposed uncompensated care payments). As described in Column 2, the proposed annual hospital update for hospitals paid under the national standardized amount, combined with the proposed annual hospital update for hospitals paid under the hospital-specific rates are expected to result in a 2.2 percent increase in payments in FY 2027 relative to FY 2026 for all hospitals. As described in Column 4, proposed uncompensated care payments would result in a 0.2 percent decrease in payments in FY 2027 relative to FY 2026 for all hospitals.

Overall payments to hospitals paid under the IPPS are estimated to increase by 1.2 percent for FY 2027 (as compared to FY 2026) due to the proposed outlier

adjustment, the proposed applicable percentage increase, the MDH program expiration, proposed uncompensated care payments, and proposed changes to the wage index. Hospitals in urban areas would experience a 1.2 percent increase in payments per discharge in FY 2027 compared to FY 2026. Hospital payments per discharge in rural areas are estimated to increase by 0.8 percent in FY 2027. The relatively lower projected increase for rural hospitals is due in part to the MDH program expiration (Column 3) and the proposed MS-DRG and relative weight changes with the application of budget neutrality (Column 5). Hospital categories that

generally treat relatively less complex cases, such as rural hospitals and smaller urban hospitals, are expected to experience a decrease in their payments, while hospitals that generally treat relatively more complex cases, such as larger urban hospitals, are expected to experience an increase in their payments as a result of the proposed changes to the relative weights.

### 3. Estimated Average Payments per Discharge

Table II displays the results of our analysis of the proposed changes for FY 2027 on estimated average payments per discharge for IPPS operating costs and

uncompensated care payments. It presents the impact for the categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2026 with the estimated average payments per discharge for FY 2027, as calculated under our models. It reflects the combined effects of the proposed changes presented in Table I, and therefore the estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

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**TABLE II.—IMPACT ANALYSIS OF PROPOSED CHANGES ON  
AVERAGE PAYMENTS PER DISCHARGE FOR OPERATING COSTS AND  
UNCOMPENSATED CARE**

|                                   | Number of Hospitals<br>(1) | Estimated Average FY<br>2026 Payment Per<br>Discharge<br>(2) | Estimated Proposed Average<br>FY 2027 Payment Per<br>Discharge<br>(3) | Proposed FY 2027<br>Changes<br>(4) |
|-----------------------------------|----------------------------|--------------------------------------------------------------|-----------------------------------------------------------------------|------------------------------------|
| <b>All Hospitals</b>              | 3,013                      | 18,984                                                       | 19,214                                                                | 1.2                                |
| <b>By Geographic Location:</b>    |                            |                                                              |                                                                       |                                    |
| Urban hospitals                   | 2,357                      | 19,462                                                       | 19,704                                                                | 1.2                                |
| Rural hospitals                   | 656                        | 13,488                                                       | 13,589                                                                | 0.8                                |
| <b>Bed Size (Urban):</b>          |                            |                                                              |                                                                       |                                    |
| 0-99 beds                         | 639                        | 13,847                                                       | 13,848                                                                | 0.0                                |
| 100-199 beds                      | 673                        | 15,153                                                       | 15,310                                                                | 1.0                                |
| 200-299 beds                      | 401                        | 16,937                                                       | 17,108                                                                | 1.0                                |
| 300-499 beds                      | 391                        | 19,015                                                       | 19,253                                                                | 1.3                                |
| 500 or more beds                  | 251                        | 24,751                                                       | 25,144                                                                | 1.6                                |
| <b>Bed Size (Rural):</b>          |                            |                                                              |                                                                       |                                    |
| 0-49 beds                         | 316                        | 11,621                                                       | 11,543                                                                | -0.7                               |
| 50-99 beds                        | 175                        | 12,821                                                       | 12,779                                                                | -0.3                               |
| 100-149 beds                      | 95                         | 12,778                                                       | 12,916                                                                | 1.1                                |
| 150-199 beds                      | 41                         | 14,383                                                       | 14,535                                                                | 1.1                                |
| 200 or more beds                  | 29                         | 16,625                                                       | 17,046                                                                | 2.5                                |
| <b>Urban by Region:</b>           |                            |                                                              |                                                                       |                                    |
| New England                       | 102                        | 20,593                                                       | 21,275                                                                | 3.3                                |
| Middle Atlantic                   | 272                        | 22,744                                                       | 23,005                                                                | 1.1                                |
| East North Central                | 364                        | 18,340                                                       | 18,406                                                                | 0.4                                |
| West North Central                | 155                        | 17,980                                                       | 18,312                                                                | 1.8                                |
| South Atlantic                    | 393                        | 17,362                                                       | 17,555                                                                | 1.1                                |
| East South Central                | 140                        | 16,021                                                       | 16,317                                                                | 1.8                                |
| West South Central                | 357                        | 18,596                                                       | 18,724                                                                | 0.7                                |
| Mountain                          | 177                        | 18,578                                                       | 18,757                                                                | 1.0                                |
| Pacific                           | 346                        | 23,067                                                       | 23,412                                                                | 1.5                                |
| <b>Rural by Region:</b>           |                            |                                                              |                                                                       |                                    |
| New England                       | 19                         | 18,113                                                       | 18,556                                                                | 2.4                                |
| Middle Atlantic                   | 47                         | 15,310                                                       | 15,497                                                                | 1.2                                |
| East North Central                | 106                        | 12,932                                                       | 12,880                                                                | -0.4                               |
| West North Central                | 72                         | 13,550                                                       | 13,672                                                                | 0.9                                |
| South Atlantic                    | 109                        | 12,704                                                       | 12,788                                                                | 0.7                                |
| East South Central                | 122                        | 11,895                                                       | 12,007                                                                | 0.9                                |
| West South Central                | 117                        | 11,759                                                       | 11,754                                                                | 0.0                                |
| Mountain                          | 40                         | 15,164                                                       | 15,384                                                                | 1.5                                |
| Pacific                           | 24                         | 17,532                                                       | 17,793                                                                | 1.5                                |
| <b>Puerto Rico</b>                |                            |                                                              |                                                                       |                                    |
| Puerto Rico Hospitals             | 51                         | 15,352                                                       | 15,051                                                                | -2.0                               |
| <b>By Payment Classification:</b> |                            |                                                              |                                                                       |                                    |
| Urban hospitals                   | 1,528                      | 16,869                                                       | 17,092                                                                | 1.3                                |
| Rural areas                       | 1,485                      | 20,353                                                       | 20,588                                                                | 1.2                                |
| <b>Teaching Status:</b>           |                            |                                                              |                                                                       |                                    |
| Nonteaching                       | 1,710                      | 13,966                                                       | 14,101                                                                | 1.0                                |
| Fewer than 100 residents          | 997                        | 16,820                                                       | 17,004                                                                | 1.1                                |
| 100 or more residents             | 306                        | 28,423                                                       | 28,842                                                                | 1.5                                |
| <b>Urban DSH:</b>                 |                            |                                                              |                                                                       |                                    |
| Non-DSH                           | 355                        | 13,744                                                       | 13,978                                                                | 1.7                                |
| 100 or more beds                  | 837                        | 17,792                                                       | 18,027                                                                | 1.3                                |
| Less than 100 beds                | 336                        | 13,213                                                       | 13,264                                                                | 0.4                                |
| <b>Rural DSH:</b>                 |                            |                                                              |                                                                       |                                    |
| Non-DSH                           | 114                        | 16,448                                                       | 16,542                                                                | 0.6                                |
| SCH                               | 222                        | 14,375                                                       | 14,550                                                                | 1.2                                |
| RRC                               | 920                        | 21,125                                                       | 21,382                                                                | 1.2                                |
| 100 or more beds                  | 41                         | 18,842                                                       | 19,081                                                                | 1.3                                |
| Less than 100 beds                | 188                        | 11,340                                                       | 11,087                                                                | -2.2                               |
| <b>Urban teaching and DSH:</b>    |                            |                                                              |                                                                       |                                    |
| Both teaching and DSH             | 483                        | 19,496                                                       | 19,772                                                                | 1.4                                |
| Teaching and no DSH               | 62                         | 15,135                                                       | 15,346                                                                | 1.4                                |
| No teaching and DSH               | 690                        | 14,619                                                       | 14,764                                                                | 1.0                                |
| No teaching and no DSH            | 293                        | 12,809                                                       | 13,058                                                                | 1.9                                |
| <b>Special Hospital Types:</b>    |                            |                                                              |                                                                       |                                    |
| SCH                               | 425                        | 15,982                                                       | 16,279                                                                | 1.9                                |

|                                                                                                                                           | Number of Hospitals<br>(1) | Estimated Average FY<br>2026 Payment Per<br>Discharge<br>(2) | Estimated Proposed Average<br>FY 2027 Payment Per<br>Discharge<br>(3) | Proposed FY 2027<br>Changes<br>(4) |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------------------------------------------------|-----------------------------------------------------------------------|------------------------------------|
| MDH                                                                                                                                       | 160                        | 12,972                                                       | 11,982                                                                | -7.6                               |
| <b>Type of Ownership:</b>                                                                                                                 |                            |                                                              |                                                                       |                                    |
| Voluntary                                                                                                                                 | 1,909                      | 18,644                                                       | 18,875                                                                | 1.2                                |
| Proprietary                                                                                                                               | 693                        | 16,919                                                       | 17,083                                                                | 1.0                                |
| Government                                                                                                                                | 409                        | 23,630                                                       | 23,934                                                                | 1.3                                |
| <b>Medicare Utilization as a<br/>Percent of Inpatient Days:</b>                                                                           |                            |                                                              |                                                                       |                                    |
| 0-25                                                                                                                                      | 1,666                      | 20,937                                                       | 21,184                                                                | 1.2                                |
| 25-50                                                                                                                                     | 1,272                      | 16,750                                                       | 16,961                                                                | 1.3                                |
| 50-65                                                                                                                                     | 42                         | 16,149                                                       | 16,347                                                                | 1.2                                |
| Over 65                                                                                                                                   | 9                          | 12,058                                                       | 12,007                                                                | -0.4                               |
| <b>Medicaid Utilization as a<br/>Percent of Inpatient Days:</b>                                                                           |                            |                                                              |                                                                       |                                    |
| 0-25                                                                                                                                      | 2,009                      | 16,789                                                       | 17,011                                                                | 1.3                                |
| 25-50                                                                                                                                     | 886                        | 22,729                                                       | 22,976                                                                | 1.1                                |
| 50-65                                                                                                                                     | 88                         | 29,377                                                       | 29,588                                                                | 0.7                                |
| Over 65                                                                                                                                   | 30                         | 27,116                                                       | 27,347                                                                | 0.9                                |
| <b>FY 2027 Reclassifications:</b>                                                                                                         |                            |                                                              |                                                                       |                                    |
| All Reclassified Hospitals                                                                                                                | 1,195                      | 20,454                                                       | 20,713                                                                | 1.3                                |
| Non-Reclassified Hospitals                                                                                                                | 1,818                      | 16,650                                                       | 16,833                                                                | 1.1                                |
| Urban Hospitals Reclassified                                                                                                              | 1,007                      | 20,937                                                       | 21,206                                                                | 1.3                                |
| Urban Non-reclassified<br>Hospitals                                                                                                       | 1,368                      | 16,879                                                       | 17,069                                                                | 1.1                                |
| Rural Hospitals Reclassified<br>Full Year                                                                                                 | 276                        | 13,551                                                       | 13,688                                                                | 1.0                                |
| Rural Non-reclassified<br>Hospitals Full Year                                                                                             | 362                        | 13,420                                                       | 13,505                                                                | 0.6                                |
| All hospitals that reclassified<br>from urban to rural in<br>accordance with section<br>1886(d)(8)(E) as implemented<br>at 42 CFR 412.103 | 882                        | 21,298                                                       | 21,550                                                                | 1.2                                |
| Other Reclassified Hospitals<br>(Section 1886(d)(8)(B), also<br>known as Lugar hospitals)                                                 | 53                         | 12,803                                                       | 12,739                                                                | -0.5                               |

**BILLING CODE 4120-01-C***G. Proposed Effects of Other Policy Changes*

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. As noted in section I.D. of this Appendix, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain proposed changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes using that payment simulation model. For these proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

1. Effects of the Proposed Changes Relating to New Medical Service and Technology Add-On Payments

a. Proposed FY 2027 Status of Technologies Approved for FY 2026 New Technology Add-On Payments

In section II.E.4. of the preamble of this proposed rule, we are proposing to continue to make new technology add-on payments for the technologies listed in the following table in FY 2027 because these technologies would still be considered new for purposes of new technology add-on payments. Under § 412.88(a)(2), the new technology add-on payment for each case would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as Qualified Infectious Disease Products (QIDPs) or approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway, or for the gene therapies, Casgevy™ (exagamglogene autotemcel) and Lyfgenia™ (lovotibeglogene autotemcel), when indicated and used specifically for the treatment of SCD, which were approved

for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69128 through 69135, and 89 FR 69188 through 69196)); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS-DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs; for technologies approved under the LPAD pathway; or for the gene therapies, Casgevy™ and Lyfgenia™, when indicated and used specifically for the treatment of SCD, which were approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69128 through 69135, and 89 FR 69188 through 69196)). Because it is difficult to predict the actual new technology add-on payment for each case, our estimates in this proposed rule are based on the applicant's estimate at the time they submitted their original application and the increase in new technology add-on payments for FY 2027 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment.

In the following table are estimates for which we are proposing to continue in  
the 41 new technology add-on payments FY 2027:  
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| <b>FY 2027 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS PROPOSED TO CONTINUE FOR FY 2027</b> |                                                                       |                        |                                                  |                                       |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|------------------------|--------------------------------------------------|---------------------------------------|
|                                                                                              | <b>Technology Name</b>                                                | <b>Estimated Cases</b> | <b>Proposed FY 2027 NTAP Amount (65% or 75%)</b> | <b>Estimated Total FY 2027 Impact</b> |
| 1                                                                                            | Annalise Enterprise CTB Triage - OH                                   | 271,200                | \$241.39                                         | \$65,464,968.00                       |
| 2                                                                                            | AStar® System                                                         | 69,000                 | \$97.50                                          | \$6,727,500.00                        |
| 3                                                                                            | Edwards EVOQUE™ Tricuspid Valve Replacement System ("EVOQUE™System")  | 800                    | \$31,850.00                                      | \$25,480,000.00                       |
| 4                                                                                            | GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) | 518                    | \$47,238.75                                      | \$24,469,672.50                       |
| 5                                                                                            | LimFlow™ System                                                       | 561                    | \$16,250.00                                      | \$9,116,250.00                        |
| 6                                                                                            | Paradise™ Ultrasound Renal Denervation System                         | 200                    | \$14,950.00                                      | \$2,990,000.00                        |
| 7                                                                                            | PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter                | 3,402                  | \$6,337.50                                       | \$21,560,175.00                       |
| 8                                                                                            | Symplcity Spyral™ Multi-Electrode Renal Denervation Catheter          | 55                     | \$10,400.00                                      | \$572,000.00                          |
| 9                                                                                            | TriClip™ G4                                                           | 150                    | \$26,000.00                                      | \$3,900,000.00                        |
| 10                                                                                           | VADER® Pedicle System                                                 | 200                    | \$28,242.50                                      | \$5,648,500.00                        |
| 11                                                                                           | ZEVTERA™ (ceftobiprole medocartil); ABSSI and CABP indications        | 245                    | \$5,287.50                                       | \$1,295,437.50                        |
| 12                                                                                           | ZEVTERA™ (ceftobiprole medocartil); SAB indication                    | 571                    | \$16,215.00                                      | \$9,258,765.00                        |
| 13                                                                                           | CASGEVY™ (exagamglogene autotemcel); Sickle Cell Disease indication   | 117                    | \$1,650,000.00                                   | \$193,050,000.00                      |
| 14                                                                                           | HEPZATO™ KIT (melphalan for injection/hepatic delivery system)        | 149                    | \$118,625.00                                     | \$17,675,125.00                       |
| 15                                                                                           | LYFGENIA™ (lovotibeglogene autotemcel)                                | 40                     | \$2,325,000.00                                   | \$93,000,000.00                       |
| 16                                                                                           | 4WEB Medical Ankle Truss System                                       | 124                    | \$15,275.00                                      | \$1,894,100.00                        |
| 17                                                                                           | AeroPace® System                                                      | 550                    | \$23,650.90                                      | \$13,007,995.00                       |
| 18                                                                                           | AGENT™ Paclitaxel-Coated Balloon Catheter                             | 9,010                  | \$4,013.75                                       | \$36,163,887.50                       |
| 19                                                                                           | alfapump® system                                                      | 200                    | \$21,450.00                                      | \$4,290,000.00                        |
| 20                                                                                           | aprevo®-C cervical interbody fusion device                            | 400                    | \$21,125.00                                      | \$8,450,000.00                        |
| 21                                                                                           | CERAMENT® G                                                           | 466                    | \$5,687.50                                       | \$2,650,375.00                        |
| 22                                                                                           | Emily's Care Nourish Test System (Model 1)                            | 11                     | \$3,347.50                                       | \$36,822.50                           |
| 23                                                                                           | Esprit™ BTK Everolimus Eluting Resorbable Scaffold System             | 5,300                  | \$6,922.50                                       | \$36,689,250.00                       |
| 24                                                                                           | EUROPA™ Posterior Cervical Fusion System                              | 849                    | \$80,548.00                                      | \$68,385,252.00                       |
| 25                                                                                           | iFuse TORQ TNT™ Implant System                                        | 1,392                  | \$4,135.95                                       | \$5,757,242.40                        |
| 26                                                                                           | Merit Wrapsody® Cell Impermeable Endoprosthesis (CIE)                 | 936                    | \$3,770.00                                       | \$3,528,720.00                        |
| 27                                                                                           | Minima Stent System                                                   | 10                     | \$22,685.00                                      | \$226,850.00                          |
| 28                                                                                           | MY01 Continuous Compartmental Pressure Monitor                        | 2,000                  | \$2,112.50                                       | \$4,225,000.00                        |
| 29                                                                                           | PBC Separator with Selux AST System                                   | 68,149                 | \$87.78                                          | \$5,982,119.22                        |
| 30                                                                                           | restor3d TIDAL™ Fusion Cage                                           | 96                     | \$18,196.75                                      | \$1,746,888.00                        |
| 31                                                                                           | ShortCut™                                                             | 550                    | \$9,750.00                                       | \$5,362,500.00                        |
| 32                                                                                           | The WiSE CRT System                                                   | 209                    | \$41,145.00                                      | \$8,599,305.00                        |
| 33                                                                                           | TriVerity Test                                                        | 5,755                  | \$243.75                                         | \$1,402,781.25                        |
| 34                                                                                           | VITEK® REVEAL™ AST System                                             | 19,000                 | \$81.25                                          | \$1,543,750.00                        |
| 35                                                                                           | EMBLAVEO™ (aztreonam-avibactam)                                       | 207                    | \$9,000.68                                       | \$1,863,140.76                        |
| 36                                                                                           | CONTEPO™ (fosfomycin)                                                 | 573                    | \$8,775.00                                       | \$5,028,075.00                        |
| 37                                                                                           | AURLUMYN™ (iloprost injection)                                        | 300                    | \$28,600.00                                      | \$8,580,000.00                        |
| 38                                                                                           | BREYANZI® (lisocabtagene maraleucel)                                  | 290                    | \$316,860.05                                     | \$91,889,414.50                       |
| 39                                                                                           | GRAFAPEX™ (treosulfan)                                                | 368                    | \$21,411.00                                      | \$7,879,248.00                        |
| 40                                                                                           | IMDELLTRA® (tarlatamab-dlle)                                          | 692                    | \$7,117.50                                       | \$4,925,310.00                        |
| 41                                                                                           | TECELRA® (afamitresgene autoleucel)                                   | 55                     | \$472,550.00                                     | \$25,990,250.00                       |
| <b>Aggregate Estimated Total FY 2027 Impact</b>                                              |                                                                       |                        |                                                  | <b>\$836,306,669.13</b>               |

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## b. Proposed FY 2027 Applications for New Technology Add-On Payments

In sections II.E.5. and 6. of the preamble to this proposed rule are 30 discussions of technologies with respect to add-on payments for new medical services and technologies for FY 2027. We note that of the 47 applications (32 alternative and 15 traditional) we received, 17 applicants (10 alternative and 7 traditional) either withdrew their applications or were not eligible for consideration for new technology add-on payment for FY 2027. As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral.

As discussed in section II.E.6. of the preamble of this proposed rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation, approved through the FDA LPAD pathway, or are designated under the Breakthrough Device program will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still be within the 2- to 3-year newness period, as discussed in section II.E.1.a.(1). of the preamble this proposed rule, and must also still meet the cost criterion.

As fully discussed in section II.E.6. of the preamble of this proposed rule, we are proposing to approve 22 new technology add-on payments for the alternative pathway applications submitted for FY 2027 new technology add-on payments.

Based on preliminary information from the applicants at the time of this proposed rule, we estimate that total payments for the technologies that applied under the alternative pathway, if approved, would be approximately \$589 million for FY 2027. Because cost or volume information has not yet been provided for 1 of the 22 technologies under the alternative pathway, we have not included that technology in the estimate. We note that the estimated payments may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We have not yet determined whether any of the technologies discussed in section II.E.5. of the preamble of this proposed rule will meet the criteria for new technology add-on payments for FY

2027 under the traditional pathway. Consequently, it is premature to estimate the potential payment impact of these technologies for any potential new technology add-on payments for FY 2027. We note that, as in past years, if any of the technologies that applied under the traditional pathway are found to be eligible for new technology add-on payments for FY 2027, we would discuss the estimated payment impact for FY 2027 in the FY 2027 IPPS/LTCH PPS final rule.

## 2. Medicare DSH Uncompensated Care Payments and Supplemental Payment for Indian Health Service Hospitals and Tribal Hospitals and Hospitals Located in Puerto Rico

As discussed in section V.E. of the preamble of this proposed rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has reported uncompensated care. Each hospital that is eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this proposed rule, we are proposing to establish the amount to be distributed as uncompensated care payments (UCP) to DSH-eligible hospitals for FY 2027, which is \$7,460,212,500. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 65.00 percent. For FY 2026, the amount available to be distributed for uncompensated care was \$7,713,127,500, or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment

adjustments adjusted by a Factor 2 of 62.14 percent. In addition, eligible IHS/Tribal hospitals and hospitals located in Puerto Rico are estimated to receive approximately \$102,768,418.04 in supplemental payments in FY 2027, based on the difference between each hospital's base year amount (that is, each hospital's FY 2022 UCP adjusted by 1 plus the percent change in the aggregate amount of uncompensated care payments between FYs 2022 and 2027) and its FY 2027 UCP. *See* 42 CFR 412.106(h)(3). If this difference is less than or equal to zero, the hospital will not receive a supplemental payment. For this proposed rule, the total proposed UCP and proposed supplemental payments equals approximately \$7.563 billion. For FY 2027, we are proposing to use 3 years of data on uncompensated care costs from Worksheet S-10 of the FYs 2021, 2022, and 2023 cost reports to calculate Factor 3 for all DSH-eligible hospitals, including IHS/Tribal hospitals and Puerto Rico hospitals. For a complete discussion regarding the methodology for calculating Factor 3 for FY 2027, we refer readers to section V.E. of the preamble of this proposed rule. For a discussion regarding the methodology for calculating the supplemental payments, we refer readers to section V.D. of the preamble of this proposed rule.

To estimate the impact of the combined effect of the proposed changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare UCP along with changes to supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico, we compared total UCP and supplemental payments estimated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536) to the combined total of the proposed UCP and the proposed supplemental payments estimated in this FY 2027 IPPS/LTCH PPS proposed rule. For FY 2026, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 62.14 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2026 IPPS/LTCH PPS final rule. For FY 2027, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments during FY 2026 absent section 3133 of the Affordable Care Act, adjusted by a proposed Factor 2 of 65.00 percent and multiplied by a Factor 3 calculated using the methodology described

previously. For this proposed rule, the supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals are calculated as the difference between the hospital's base year amount and the hospital's FY 2027 UCP.

Our analysis included 2,318 hospitals that are projected to be DSH-eligible in FY 2027. Our analysis did not include hospitals that had terminated their participation in the Medicare program as of February 3, 2026, Maryland

hospitals, new hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. The 22 hospitals that are anticipated to be participating in the Rural Community Hospital Demonstration Program were also excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and UCP. In addition, the data from merged or acquired hospitals were combined under the

surviving hospital's CMS certification number (CCN), and the non-surviving CCN was excluded from the analysis. The estimated impact of the proposed changes in Factors 1, 2, and 3 on UCP and supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals across all hospitals projected to be DSH-eligible in FY 2027, by hospital characteristic, is presented in the following table:

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| <b>MODELED UNCOMPENSATED CARE PAYMENTS* AND SUPPLEMENTAL PAYMENTS FOR<br/>ESTIMATED FY 2027 DSHS BY HOSPITAL TYPE</b> |                                                 |                                                                                                                             |                                                                                                                              |                                                                                          |                                      |
|-----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|--------------------------------------|
|                                                                                                                       | <b>Number of<br/>Estimated<br/>DSHs<br/>(1)</b> | <b>FY 2026 Estimated<br/>Uncompensated<br/>Care Payments and<br/>Supplemental<br/>Payments<br/>(\$ in millions)<br/>(2)</b> | <b>FY 2027 Proposed<br/>Uncompensated Care<br/>Payments and<br/>Supplemental<br/>Payments**<br/>(\$ in millions)<br/>(3)</b> | <b>Dollar<br/>Difference:<br/>FY 2026 -<br/>FY 2027<br/>(\$ in<br/>millions)<br/>(4)</b> | <b>Percent<br/>Change***<br/>(5)</b> |
| <b>Total</b>                                                                                                          | <b>2,318</b>                                    | <b>\$7,821</b>                                                                                                              | <b>\$7,563</b>                                                                                                               | <b>-\$258</b>                                                                            | <b>-3.3%</b>                         |
| <b>By Geographic Location</b>                                                                                         |                                                 |                                                                                                                             |                                                                                                                              |                                                                                          |                                      |
| Urban Hospitals                                                                                                       | 1,870                                           | 7,384                                                                                                                       | 7,163                                                                                                                        | -221                                                                                     | -3.0                                 |
| Other Urban Areas                                                                                                     | 963                                             | 3,240                                                                                                                       | 3,090                                                                                                                        | -149                                                                                     | -4.6                                 |
| Large Urban Areas                                                                                                     | 907                                             | 4,144                                                                                                                       | 4,073                                                                                                                        | -72                                                                                      | -1.7                                 |
| Rural Hospitals                                                                                                       | 448                                             | 437                                                                                                                         | 400                                                                                                                          | -37                                                                                      | -8.5                                 |
| <b>Bed Size (Urban)</b>                                                                                               |                                                 |                                                                                                                             |                                                                                                                              |                                                                                          |                                      |
| 0 to 99 Beds                                                                                                          | 355                                             | 316                                                                                                                         | 291                                                                                                                          | -24                                                                                      | -7.7                                 |
| 100 to 249 Beds                                                                                                       | 761                                             | 1,583                                                                                                                       | 1,522                                                                                                                        | -61                                                                                      | -3.9                                 |
| 250+ Beds                                                                                                             | 754                                             | 5,485                                                                                                                       | 5,350                                                                                                                        | -135                                                                                     | -2.5                                 |
| <b>Bed Size (Rural)</b>                                                                                               |                                                 |                                                                                                                             |                                                                                                                              |                                                                                          |                                      |
| 0 to 99 Beds                                                                                                          | 333                                             | 232                                                                                                                         | 212                                                                                                                          | -20                                                                                      | -8.5                                 |
| 100 to 249 Beds                                                                                                       | 106                                             | 165                                                                                                                         | 152                                                                                                                          | -13                                                                                      | -7.9                                 |
| 250+ Beds                                                                                                             | 9                                               | 40                                                                                                                          | 35                                                                                                                           | -4                                                                                       | -10.8                                |
| <b>Urban by Region</b>                                                                                                |                                                 |                                                                                                                             |                                                                                                                              |                                                                                          |                                      |
| New England                                                                                                           | 85                                              | 203                                                                                                                         | 199                                                                                                                          | -5                                                                                       | -2.4                                 |
| Middle Atlantic                                                                                                       | 218                                             | 867                                                                                                                         | 877                                                                                                                          | 10                                                                                       | 1.1                                  |
| South Atlantic                                                                                                        | 298                                             | 738                                                                                                                         | 682                                                                                                                          | -56                                                                                      | -7.5                                 |
| East North Central                                                                                                    | 101                                             | 363                                                                                                                         | 326                                                                                                                          | -37                                                                                      | -10.3                                |
| East South Central                                                                                                    | 307                                             | 1,896                                                                                                                       | 1,828                                                                                                                        | -68                                                                                      | -3.6                                 |
| West North Central                                                                                                    | 123                                             | 471                                                                                                                         | 456                                                                                                                          | -15                                                                                      | -3.2                                 |
| West South Central                                                                                                    | 243                                             | 1,729                                                                                                                       | 1,710                                                                                                                        | -20                                                                                      | -1.1                                 |
| Mountain                                                                                                              | 143                                             | 348                                                                                                                         | 354                                                                                                                          | 6                                                                                        | 1.7                                  |
| Pacific                                                                                                               | 308                                             | 670                                                                                                                         | 640                                                                                                                          | -31                                                                                      | -4.6                                 |
| Puerto Rico                                                                                                           | 44                                              | 98                                                                                                                          | 92                                                                                                                           | -5                                                                                       | -5.6                                 |
| <b>Rural by Region</b>                                                                                                |                                                 |                                                                                                                             |                                                                                                                              |                                                                                          |                                      |
| New England                                                                                                           | 9                                               | 11                                                                                                                          | 12                                                                                                                           | 2                                                                                        | 14.0                                 |
| Middle Atlantic                                                                                                       | 35                                              | 25                                                                                                                          | 25                                                                                                                           | 0                                                                                        | -0.4                                 |
| South Atlantic                                                                                                        | 63                                              | 55                                                                                                                          | 46                                                                                                                           | -9                                                                                       | -16.6                                |
| East North Central                                                                                                    | 30                                              | 27                                                                                                                          | 24                                                                                                                           | -3                                                                                       | -12.7                                |
| East South Central                                                                                                    | 83                                              | 124                                                                                                                         | 114                                                                                                                          | -10                                                                                      | -8.2                                 |
| West North Central                                                                                                    | 99                                              | 82                                                                                                                          | 76                                                                                                                           | -6                                                                                       | -7.4                                 |
| West South Central                                                                                                    | 103                                             | 92                                                                                                                          | 84                                                                                                                           | -8                                                                                       | -8.5                                 |
| Mountain                                                                                                              | 19                                              | 13                                                                                                                          | 12                                                                                                                           | -1                                                                                       | -10.5                                |
| Pacific                                                                                                               | 7                                               | 7                                                                                                                           | 7                                                                                                                            | 0                                                                                        | -3.7                                 |
| <b>By Payment Classification</b>                                                                                      |                                                 |                                                                                                                             |                                                                                                                              |                                                                                          |                                      |
| Urban Hospitals                                                                                                       | 1,156                                           | 3,226                                                                                                                       | 3,142                                                                                                                        | -84                                                                                      | -2.6                                 |
| Large Urban Areas                                                                                                     | 619                                             | 1,974                                                                                                                       | 1,937                                                                                                                        | -36                                                                                      | -1.8                                 |
| Other Urban Areas                                                                                                     | 537                                             | 1,252                                                                                                                       | 1,205                                                                                                                        | -48                                                                                      | -3.8                                 |
| Rural Hospitals                                                                                                       | 1,162                                           | 4,595                                                                                                                       | 4,421                                                                                                                        | -174                                                                                     | -3.8                                 |
| <b>Teaching Status</b>                                                                                                |                                                 |                                                                                                                             |                                                                                                                              |                                                                                          |                                      |
| Nonteaching                                                                                                           | 1,186                                           | 1,782                                                                                                                       | 1,697                                                                                                                        | -85                                                                                      | -4.8                                 |
| Fewer than 100 residents                                                                                              | 833                                             | 2,797                                                                                                                       | 2,675                                                                                                                        | -122                                                                                     | -4.4                                 |
| 100 or more residents                                                                                                 | 299                                             | 3,242                                                                                                                       | 3,191                                                                                                                        | -51                                                                                      | -1.6                                 |
| <b>Type of Ownership</b>                                                                                              |                                                 |                                                                                                                             |                                                                                                                              |                                                                                          |                                      |
| Voluntary                                                                                                             | 1,489                                           | 4,468                                                                                                                       | 4,302                                                                                                                        | -167                                                                                     | -3.7                                 |

### MODELED UNCOMPENSATED CARE PAYMENTS\* AND SUPPLEMENTAL PAYMENTS FOR ESTIMATED FY 2027 DSHS BY HOSPITAL TYPE

|                                             | Number of<br>Estimated<br>DSHs<br>(1) | FY 2026 Estimated<br>Uncompensated<br>Care Payments and<br>Supplemental<br>Payments<br>(\$ in millions)<br>(2) | FY 2027 Proposed<br>Uncompensated Care<br>Payments and<br>Supplemental<br>Payments**<br>(\$ in millions)<br>(3) | Dollar<br>Difference:<br>FY 2026 -<br>FY 2027<br>(\$ in<br>millions)<br>(4) | Percent<br>Change***<br>(5) |
|---------------------------------------------|---------------------------------------|----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|-----------------------------|
| Proprietary                                 | 469                                   | 1,070                                                                                                          | 1,011                                                                                                           | -60                                                                         | -5.6                        |
| Government                                  | 360                                   | 2,282                                                                                                          | 2,251                                                                                                           | -32                                                                         | -1.4                        |
| <b>Medicare Utilization<br/>Percent****</b> |                                       |                                                                                                                |                                                                                                                 |                                                                             |                             |
| 0 to 25                                     | 1,478                                 | 6,338                                                                                                          | 6,181                                                                                                           | -157                                                                        | -2.5                        |
| 25 to 50                                    | 824                                   | 1,476                                                                                                          | 1,375                                                                                                           | -101                                                                        | -6.8                        |
| 50 to 65                                    | 15                                    | 7                                                                                                              | 6                                                                                                               | -1                                                                          | -7.8                        |
| Greater than 65                             | 1                                     | 0                                                                                                              | 0                                                                                                               | 0                                                                           | 0.0                         |
| <b>Medicaid Utilization<br/>Percent****</b> |                                       |                                                                                                                |                                                                                                                 |                                                                             |                             |
| 0 to 25                                     | 1,364                                 | 3,541                                                                                                          | 3,373                                                                                                           | -168                                                                        | -4.7                        |
| 25 to 50                                    | 832                                   | 3,501                                                                                                          | 3,414                                                                                                           | -87                                                                         | -2.5                        |
| 50 to 65                                    | 91                                    | 692                                                                                                            | 688                                                                                                             | -3                                                                          | -0.5                        |
| Greater than 65                             | 31                                    | 88                                                                                                             | 88                                                                                                              | 1                                                                           | 0.8                         |

Source: Dobson | DaVanzo analysis of 2021, 2022 and 2023 Hospital Cost Reports.

\*Dollar UCP calculated by  $[0.75 * \text{estimated section 1886(d)(5)(F) payments} * \text{Factor 2} * \text{Factor 3}]$ . When summed across all hospitals projected to receive DSH payments, UCP and supplemental payments are estimated to be \$7.821 billion in FY 2026, and UCP and supplemental payments are estimated to be \$7.563 billion in FY 2027.

\*\* For IHS/Tribal hospitals and Puerto Rico hospitals, this impact table reflects the supplemental payments.

\*\*\* Percentage change is determined as the difference between Medicare UCP and supplemental payments modeled for this FY 2027 IPPS/LTCH PPS proposed rule (column 3) and Medicare UCP and supplemental payments modeled for the FY 2026 IPPS/LTCH PPS final rule (column 2) divided by Medicare UCP and supplemental payments modeled for the FY 2026 IPPS/LTCH PPS final rule (column 2) times 100 percent.

\*\*\*\*Hospitals with missing or unknown Medicare utilization or Medicaid utilization are not shown in the table.

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The changes in projected FY 2027 UCP and supplemental payments compared to the total of UCP and supplemental payments in FY 2026 are driven by a decrease in Factor 1 and a slight increase in Factor 2. Proposed Factor 1 has decreased slightly from the FY 2026 final rule's Factor 1 of \$12.412 billion to this proposed rule's Factor 1 of \$11.477 billion. Proposed Factor 2 has increased from the FY 2026 final rule's Factor 2 of 62.14 percent to this proposed rule's Factor 2 of 65.00 percent. In addition, we note that there is a slight decrease in the number of projected DSH-eligible hospitals to 2,318 at the time of the development of this proposed rule compared to the 2,364 DSHs at the time of development of the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536). Based on the changes, the impact analysis found that, across all projected DSH-eligible hospitals, proposed FY 2027 UCP and proposed supplemental payments are estimated at approximately \$7.563 billion, or a decrease of approximately

3.3 percent from FY 2026 UCP and supplemental payments (approximately \$7.821 billion). While the changes would result in a net decrease in the proposed total amount available to be distributed in UCP and supplemental payments, the projected payment changes vary by hospital type. This redistribution of payments is caused by changes in Factor 3 and the amount of the supplemental payment for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals. As seen in the previous table, a percent change greater than -3.3 percent indicates that hospitals within the specified category are projected to experience a smaller decrease in payments, on average, compared to the universe of projected FY 2026 DSH-eligible hospitals. Conversely, a percentage change less than -3.3 percent indicates that a hospital type is projected to have a larger decrease compared to the overall average. The variation in the distribution of overall payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported

on the Worksheet S-10 and used in the Factor 3 computation and whether the hospital is eligible to receive the supplemental payment.

Rural hospitals, in general, are projected to experience a larger change in UCP compared to the decrease their urban counterparts are projected to experience. Overall, rural hospitals are projected to receive a -8.5 percent change in payments, while urban hospitals are projected to receive a -3.0 percent change in payments, which is slightly above the overall hospital average.

By bed size, rural hospitals with 0 to 99 beds, 100 to 249 beds, and 250+ beds are projected to have percent change of approximately -8.5 percent, -7.9 percent, and -10.8 percent, respectively. Among urban hospitals, the largest urban hospitals, those with 250+ beds, are projected to receive a decrease in payments (-2.5 percent). In contrast, smaller urban hospitals with 0-99 beds and 100-249 beds are projected to receive percent change in payments of -7.7 and -3.9 percent, respectively.

By region, rural hospitals are projected to receive a varied range of payment changes. Rural hospitals in New England are projected to receive an increase in payments and those in the Middle Atlantic region are projected to receive smaller than average decreases in payments. However, rural hospitals in all other regions including the Pacific, South Atlantic, East North Central, East South Central, West North Central, West South Central, and Mountain regions are projected to receive larger than average decreases in payments. Similarly, urban hospitals are projected to receive a varied range of payment changes. Urban hospitals in the Middle Atlantic and Mountain regions are projected to receive an increase in payments, and those in the New England, West North Central, and West South Central regions are projected to receive smaller than average decreases in payments. However, urban hospitals in South Atlantic, East North Central, East South Central, Pacific regions, and Puerto Rico are projected to receive larger than average decreases in payments.

By payment classification, hospitals in urban payment areas overall are expected to receive a smaller than average change in UCP and supplemental payments of -2.6 percent. Hospitals in large urban payment areas are projected to receive a smaller than average change in payments (-1.8 percent), while other urban payment areas are projected to receive a larger than average change in payments of -3.8 percent. Hospitals in rural payment areas are projected to receive a larger than average change in payments of -3.8 percent.

Nonteaching hospitals and teaching hospitals with fewer than 100 residents are projected to receive average payment changes of -4.8 percent and -4.4 percent, respectively. Teaching hospitals with 100+ residents are projected to receive an average payment change of -1.6 percent. Voluntary hospitals and proprietary hospitals are projected to receive average changes of -3.7 percent and -5.6 percent, respectively, while government-owned hospitals are expected to receive a smaller than average payment change of -1.4 percent. Hospitals with less than 25 percent Medicare utilization are projected to receive an average change of -2.5 percent, while hospitals with Medicare utilization between 25–50 percent and 50–65 percent are projected to receive average payment changes of -6.8 percent and -7.8 percent, respectively. (Medicare utilization refers to a hospital's Medicare days divided by a hospital's total inpatient days.) We note

that there is one hospital with greater than 65 percent Medicare utilization that did not have UCP in FY 2026 and is projected to have no UCP in FY 2027. Thus, there is a zero percent change in payments for this hospital. Hospitals with 25–50 percent Medicaid utilization, those with 50–65 percent Medicaid utilization, and those with greater than 65 percent Medicaid utilization are projected to receive smaller than average changes in payments of -2.5 percent, -0.5 percent and 0.8 percent, respectively. Hospitals with less than 25 percent Medicaid utilization are projected to receive an average change of -4.7 percent. (Medicaid utilization refers to a hospital's Medicaid days divided by a hospital's total inpatient days.)

The impact table reflects the proposed FY 2027 UCP and proposed supplemental payments for IHS/Tribal and Puerto Rico hospitals. We note that the proposed supplemental payments to IHS/Tribal hospitals and Puerto Rico hospitals are estimated to be approximately \$102.8 million in FY 2027.

### 3. Effects of Expiration of Temporary Changes to the Low-Volume Hospital Payment Policy

In section V.D. of the preamble of this proposed rule, we discuss the extension of the temporary changes to the low-volume hospital payment policy originally provided for by the Affordable Care Act and extended by subsequent legislation. Specifically, section 6201 of the Consolidated Appropriations Act, 2026 further extended the modified definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12) through December 31, 2026.

Beginning January 1, 2027, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011, and the preexisting low-volume hospital payment adjustment methodology and qualifying criteria, as implemented in FY 2005, will resume. Therefore, absent further Congressional action, effective for the portion of FY 2027 occurring on or after January 1, 2027, FY 2028 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year.

Using the same methodology used in developing the quantitative analyses of changes in payments per case discussed previously in section I.G. of Appendix A of this proposed rule, based upon the best available data at this time, we estimate the expiration of the temporary changes to the low-volume hospital payment policy effective for discharges occurring on or after January 1, 2027, and subsequent years would decrease aggregate low-volume hospital payments by \$258 million in FY 2027 as compared to FY 2026. This payment estimate was determined based on the estimated payments for the approximately 589 providers that are expected to no longer qualify under the criteria that are effective beginning on January 1, 2027.

Of those 589 hospitals, currently approximately 90 hospitals have a low-volume hospital payment adjustment based on 500 or fewer total discharges, while the remaining approximately 499 hospitals have an adjustment based on having between 500 and 3,800 total discharges. Approximately 55 of the 589 hospitals that currently qualify for a low-volume hospital payment adjustment in FY 2026 have 200 or fewer total discharges. However, the distance information needed to project whether those hospitals are more than 25 road miles from another subsection (d) hospital (instead of 15 road miles), and therefore would continue to qualify for a low-volume hospital payment adjustment for FY 2027, is evaluated by each hospitals' MAC. Therefore, we are unable to estimate how many of these 55 hospitals would continue to qualify for the low-volume hospital payment adjustment for FY 2027.

### 4. Effects of Proposed Requirements To Prohibit Unlawful Discrimination by GME and NAH Education Programs.

In section V.F.2. of the preamble of this proposed rule, we discuss our proposal to require that, in addition to meeting other applicable requirements, an approved medical residency training program must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. In section V.G.3. of the preamble of this proposed rule, we discuss similar proposals with respect to approved nursing and allied health education programs and accreditors. The effective date of these policies

would be October 1, 2026. We believe that, as of October 1, 2026, no approved programs or accrediting bodies would continue to or newly engage in unlawful discrimination on the basis of race or other protected characteristics.

#### 5. Effects of Proposed Changes for Determining Net Costs of Approved NAH Education Programs

In section V.G.4. of this proposed rule, we discuss our proposal to revise the regulations at 42 CFR 413.85(d)(2) to state that tuition and other revenue must be subtracted from the allowable direct costs of a hospital's NAH education programs prior to the allocation of indirect costs. This proposal stems from an adverse ruling by the U.S. District Court for the District of Columbia in *Mercy Health—St. Vincent Medical Center LLC d/b/a Mercy St. Vincent Medical Center v. Becerra*, 717 F. Supp. 3d 33 (D.D.C. 2024). In addition, we clarify our existing policies regarding the nature of allowable indirect NAH costs and propose to require hospitals with approved, provider-operated NAH education programs to follow specific procedures to ensure correct allocation of indirect costs to the NAH cost centers. We are unable to estimate the financial impact of the proposed changes to the regulations text and the allocation process since, with the exception of the plaintiffs in the *Mercy St. Vincent* litigation, it is unclear what cost reporting procedures hospitals would employ in the absence of this rulemaking.

#### 6. Effects Under the Hospital Readmissions Reduction Program for FY 2027

In section V.I. of the preamble of this proposed rule, we are proposing to add sepsis as an applicable condition beginning with the FY 2029 program year; the remaining policies finalized in FY 2026 IPPS/LTCH PPS final rule (90 FR 36923) continue to apply. As finalized in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36923 through 36929), we will integrate Medicare Advantage beneficiaries into the cohorts of the Hospital Readmissions Reduction Program measure set and reduce the applicable period from 3 years to 2 years beginning with the FY 2027 program year.

In section V.I.2.b. of the preamble of this proposed rule, we discuss our proposal to adopt the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure beginning with

the FY 2029 program year. While we state in section XII.B.1. of the preamble of this proposed rule that adopting this measure would not result in any change in information collection burden, we acknowledge that hospitals not currently providing the types of discharge planning and care coordination services that would be expected to minimize readmissions may incur other financial impacts such as updating policies and procedures, increased governance and oversight, and staff training in order to do so. We also recognize that most hospitals have already established standard evidence-based sepsis protocols as part of their existing quality improvement and patient safety frameworks. As such, hospitals are generally well-positioned with respect to the acute clinical management of sepsis, and the additional burden associated with this proposal is more likely to center on post-discharge care coordination and transition planning rather than inpatient sepsis treatment protocols. However, because each hospital is unique and we lack insight into what services each may already offer or would elect to offer if this proposal is finalized, we are unable to estimate the costs associated with these impacts. We request public comment on financial impacts related to post-discharge coordination, transition planning, or other areas associated with the acute clinical management of sepsis that hospitals may incur if this proposal is finalized.

The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating diagnosis-related group (DRG) payments to account for excess readmissions of selected applicable conditions and procedures. The table and analysis in this section illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. Hospitals are sorted into quintiles based on the proportion of dual-eligible stays among Medicare Fee-For-Service and managed care (that is, Medicare Advantage) stays between July 1, 2021, and June 30, 2023. Hospitals' excess readmission ratios (ERRs)—based on the data used to calculate preliminary Medicare Advantage and Medicare Fee-for-Service readmission measure results from January 1, 2022, through December 31, 2023—are assessed relative to their peer group median. A neutrality modifier is applied in the payment adjustment factor calculation to maintain budget

neutrality. In the FY 2027 IPPS/LTCH PPS final rule, we will provide an updated estimate of the financial impact using the proportion of dually-eligible beneficiaries, ERRs, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2027 Hospital Readmissions Reduction Program applicable period (that is, July 1, 2023, through June 30, 2025).

The results in Table I.G.6.-01 include 2,832 non-Maryland hospitals estimated as eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between January 1, 2022, and December 31, 2023. The third column in Table I.G.6.-01 indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals).

The fourth column in Table I.G.6.-01 indicates the estimated percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 78.64 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 87.93 percent of eligible hospitals with fewer than 100 residents and 93.90 percent of eligible hospitals with 100 or more residents are expected to be penalized. The fifth column in Table I.G.6.-01 estimates the financial impact on hospitals by hospital characteristic. Table I.G.6.-01 also shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2022, through September 30, 2023 (FY 2023). For example, the penalty as a share of payments for non-teaching hospitals is 0.51 percent. This means that total penalties for all non-teaching hospitals are 0.51 percent of total payments for non-teaching hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

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**TABLE I.G.6.-01: ESTIMATED PERCENTAGE OF HOSPITALS PENALIZED AND PENALTY AS SHARE OF PAYMENTS FOR FY 2027 HOSPITAL READMISSIONS REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC**

| Hospital Characteristic                                                                     | Number of Hospitals Eligible for a Penalty <sup>(a)</sup> | Number of Penalized Hospitals <sup>(b)</sup> | Percentage of Hospitals Penalized <sup>(c)</sup> (%) | Penalty as a Share of Payments <sup>(d)</sup> (%) |
|---------------------------------------------------------------------------------------------|-----------------------------------------------------------|----------------------------------------------|------------------------------------------------------|---------------------------------------------------|
| <b>All Hospitals</b>                                                                        | 2,832                                                     | 2,358                                        | 83.26                                                | 0.48                                              |
| <b>By Geographic Location (n= 2,826)</b>                                                    |                                                           |                                              |                                                      |                                                   |
| <b>Urban hospitals</b>                                                                      | 2,180                                                     | 1,876                                        | 86.06                                                | 0.48                                              |
| 1-99 beds                                                                                   | 511                                                       | 358                                          | 70.06                                                | 0.48                                              |
| 100-199 beds                                                                                | 635                                                       | 562                                          | 88.50                                                | 0.56                                              |
| 200-299 beds                                                                                | 393                                                       | 365                                          | 92.88                                                | 0.57                                              |
| 300-399 beds                                                                                | 270                                                       | 251                                          | 92.96                                                | 0.49                                              |
| 400-499 beds                                                                                | 118                                                       | 111                                          | 94.07                                                | 0.45                                              |
| 500 or more beds                                                                            | 253                                                       | 229                                          | 90.51                                                | 0.39                                              |
| <b>Rural hospitals</b>                                                                      | 646                                                       | 480                                          | 74.30                                                | 0.47                                              |
| 1-49 beds                                                                                   | 295                                                       | 183                                          | 62.03                                                | 0.37                                              |
| 50-99 beds                                                                                  | 184                                                       | 148                                          | 80.43                                                | 0.49                                              |
| 100-149 beds                                                                                | 94                                                        | 82                                           | 87.23                                                | 0.52                                              |
| 150-199 beds                                                                                | 42                                                        | 38                                           | 90.48                                                | 0.50                                              |
| 200 or more beds                                                                            | 31                                                        | 29                                           | 93.55                                                | 0.46                                              |
| <b>By Teaching Status<sup>(e)</sup> (n= 2,826)</b>                                          |                                                           |                                              |                                                      |                                                   |
| Non-teaching                                                                                | 1,578                                                     | 1,241                                        | 78.64                                                | 0.51                                              |
| Fewer than 100 Residents                                                                    | 953                                                       | 838                                          | 87.93                                                | 0.50                                              |
| 100 or more Residents                                                                       | 295                                                       | 277                                          | 93.90                                                | 0.42                                              |
| <b>By Ownership Type (n= 2,826)</b>                                                         |                                                           |                                              |                                                      |                                                   |
| Government                                                                                  | 397                                                       | 324                                          | 81.61                                                | 0.32                                              |
| Proprietary                                                                                 | 611                                                       | 492                                          | 80.52                                                | 0.66                                              |
| Voluntary                                                                                   | 1,818                                                     | 1,540                                        | 84.71                                                | 0.47                                              |
| <b>By Safety-Net Status<sup>(f)</sup> (n= 2,826)</b>                                        |                                                           |                                              |                                                      |                                                   |
| Safety-net hospitals                                                                        | 566                                                       | 470                                          | 83.04                                                | 0.44                                              |
| Non-safety-net hospitals                                                                    | 2,260                                                     | 1,886                                        | 83.45                                                | 0.49                                              |
| <b>By Disproportionate Share Hospital (DSH) Patient Percentage<sup>(g)</sup> (n= 2,826)</b> |                                                           |                                              |                                                      |                                                   |
| 0-24                                                                                        | 1,069                                                     | 868                                          | 81.20                                                | 0.54                                              |
| 25-49                                                                                       | 1,470                                                     | 1,255                                        | 85.37                                                | 0.44                                              |
| 50-64                                                                                       | 166                                                       | 132                                          | 79.52                                                | 0.51                                              |
| 65 and over                                                                                 | 121                                                       | 101                                          | 83.47                                                | 0.58                                              |
| <b>By Medicare Cost Report (MCR) Percentage<sup>(h)</sup> (n= 2,826)</b>                    |                                                           |                                              |                                                      |                                                   |
| 0-24                                                                                        | 1,404                                                     | 1,192                                        | 84.90                                                | 0.39                                              |
| 25-49                                                                                       | 1,355                                                     | 1,124                                        | 82.95                                                | 0.56                                              |
| 50-64                                                                                       | 60                                                        | 38                                           | 63.33                                                | 0.71                                              |
| 65 and over                                                                                 | 7                                                         | 2                                            | 28.57                                                | 2.73                                              |
| <b>By Region (n= 2,831)</b>                                                                 |                                                           |                                              |                                                      |                                                   |
| New England                                                                                 | 120                                                       | 115                                          | 95.83                                                | 0.63                                              |
| Middle Atlantic                                                                             | 313                                                       | 293                                          | 93.61                                                | 0.62                                              |
| East North Central                                                                          | 443                                                       | 379                                          | 85.55                                                | 0.49                                              |
| West North Central                                                                          | 223                                                       | 176                                          | 78.92                                                | 0.38                                              |
| South Atlantic                                                                              | 485                                                       | 424                                          | 87.42                                                | 0.49                                              |
| East South Central                                                                          | 252                                                       | 208                                          | 82.54                                                | 0.43                                              |
| West South Central                                                                          | 422                                                       | 322                                          | 76.30                                                | 0.37                                              |
| Mountain                                                                                    | 206                                                       | 140                                          | 67.96                                                | 0.32                                              |
| Pacific                                                                                     | 367                                                       | 301                                          | 82.02                                                | 0.43                                              |

**Source:** The table results are based on the data used to calculate preliminary readmission measure results for Medicare Advantage and Medicare Fee-for-Service patients that were available using data from January 1, 2022, through December 31, 2023; Fee-for-Service DRG ratios and dual proportions from July 1, 2021, through June 30, 2023. Although data from all subsection (d), Maryland hospitals, and hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program (such as CAHs) were used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals, hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program, and hospitals that are not open as of the October 2025 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are sorted into five peer groups based on the proportion of Fee-for-Service and managed care dual-eligible stays from July 1, 2021, through June 30, 2023. Hospital characteristics are from the FY 2026 IPPS/LTCH PPS Proposed Rule Impact File. **Note:** The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for geographic location, teaching status, ownership type, safety-net status, DSH patient percentage, and MCR percentage (n=2,826; missing=6) and region (n=2,831; missing=1). The methodology differs from the impact analyses included in the FY 2026 IPPS/LTCH PPS final rule in that this table includes the removal of the COVID-19 exclusion, use of a two-year performance period for DRG ratio calculations, and updated input datasets.

<sup>(a)</sup> This column is the number of applicable hospitals within the characteristic that could receive a penalty (that is, they have 25 or more eligible discharges for at least one measure).

<sup>b</sup> This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

<sup>c</sup> This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

<sup>d</sup> This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments in this way allows for comparisons across hospital characteristics that accounts for differences in the amount of base operating DRG payments for different groups of hospitals. MedPAR data from October 1, 2022, through September 30, 2023 (FY 2023), are used to estimate the total base operating DRG payments.

<sup>e</sup> A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operating PPS greater than zero.

<sup>f</sup> A hospital is considered a safety-net hospital if it is in the top DSH quintile.

<sup>g</sup> DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

<sup>h</sup> MCR (Medicare Cost Report) percentage is the percentage of total inpatient stays from Medicare patients.

## 7. Effects of Proposed Changes Under the FY 2027 Hospital Value-Based Purchasing Program

The Secretary makes value-based incentive payments to hospitals under the Hospital Value-Based Purchasing Program based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2027 through a reduction to the FY 2027 base operating DRG payment amount for hospital discharges for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2027 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary. In section V.J.1.b. of the preamble of this proposed rule, we estimate the available pool of funds for value-based incentive payments in the FY 2027 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payments, or a total of

approximately \$1.9 billion. This estimated available pool for FY 2027 is based on the historical pool of hospitals that were eligible to participate in the FY 2026 program year and the payment information from the December 2025 update to the FY 2025 MedPAR file.

The proposed estimated impacts of the FY 2027 program year by hospital characteristic, found in Table I.G.8.-01, are based on historical TPSs. We used the FY 2026 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the December 2025 update to the FY 2025 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the internet on the CMS website).

The proposed estimated impact analysis shows that, for the FY 2027 program year, the number of hospitals with a positive percent change in base operating DRG (51.5 percent) is higher

than the number of hospitals with a negative percent change (48.5 percent). Approximately half of all hospitals experience a percent change in base operating DRG between -2.1 percent and 0.0 percent. On average, both urban hospitals in the West North Central region and rural hospitals in the Pacific region have the highest positive percent change in base operating DRG. Urban hospitals in the Middle Atlantic, South Atlantic, and East South Central regions experience an average negative percent change in base operating DRG. All other regions (both urban and rural) experience an average positive percent change in base operating DRG. Hospitals in higher MCR percent categories have higher average net percentage payment increases compared to hospitals with lower MCR percent. Hospitals in higher DSH percent categories (50–64 and 65 and over) have negative average net percentage payment, compared to hospitals in the lower DSH categories. On average, non-teaching hospitals have a higher percent change in base operating DRG compared to teaching hospitals.

**TABLE I.G.8.-01: IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM THE FY 2027 HOSPITAL VBP PROGRAM**

|                                |                        | Number of Hospitals | Average Net Percentage Payment Adjustment |
|--------------------------------|------------------------|---------------------|-------------------------------------------|
| <b>BY GEOGRAPHIC LOCATION:</b> |                        |                     |                                           |
|                                | <b>All Hospitals</b>   | <b>2,455</b>        | <b>0.131%</b>                             |
|                                | Urban Area             | 1,924               | 0.061%                                    |
|                                | Rural Area             | 531                 | 0.387%                                    |
|                                | <b>Urban Hospitals</b> | <b>1,924</b>        | <b>0.061%</b>                             |
|                                | 0-99 beds              | 357                 | 0.617%                                    |
|                                | 100-199 beds           | 585                 | 0.092%                                    |
|                                | 200-299 beds           | 377                 | -0.166%                                   |
|                                | 300-499 beds           | 365                 | -0.178%                                   |
|                                | 500 or more beds       | 240                 | -0.124%                                   |
|                                | <b>Rural Hospitals</b> | <b>531</b>          | <b>0.387%</b>                             |
|                                | 0-49 beds              | 202                 | 0.643%                                    |
|                                | 50-99 beds             | 170                 | 0.395%                                    |
|                                | 100-149 beds           | 92                  | 0.175%                                    |
|                                | 150-199 beds           | 38                  | -0.055%                                   |
|                                | 200 or more beds       | 29                  | -0.185%                                   |
| <b>BY REGION:</b>              |                        |                     |                                           |
|                                | <b>Urban By Region</b> | <b>1,924</b>        | <b>0.061%</b>                             |
|                                | New England            | 92                  | 0.107%                                    |
|                                | Middle Atlantic        | 247                 | -0.080%                                   |
|                                | South Atlantic         | 362                 | -0.002%                                   |
|                                | East North Central     | 278                 | 0.099%                                    |
|                                | East South Central     | 111                 | -0.126%                                   |
|                                | West North Central     | 126                 | 0.195%                                    |
|                                | West South Central     | 233                 | 0.075%                                    |
|                                | Mountain               | 156                 | 0.109%                                    |
|                                | Pacific                | 319                 | 0.171%                                    |
|                                | <b>Rural By Region</b> | <b>531</b>          | <b>0.387%</b>                             |
|                                | New England            | 16                  | 0.548%                                    |
|                                | Middle Atlantic        | 41                  | 0.302%                                    |
|                                | South Atlantic         | 89                  | 0.290%                                    |
|                                | East North Central     | 98                  | 0.491%                                    |
|                                | East South Central     | 94                  | 0.131%                                    |
|                                | West North Central     | 67                  | 0.643%                                    |
|                                | West South Central     | 69                  | 0.123%                                    |
|                                | Mountain               | 32                  | 0.805%                                    |
|                                | Pacific                | 25                  | 0.838%                                    |
| <b>BY MCR PERCENT:</b>         |                        |                     |                                           |
|                                | 0-24                   | 1,256               | 0.060%                                    |
|                                | 25-49                  | 1,161               | 0.194%                                    |
|                                | 50-64                  | 36                  | 0.527%                                    |
|                                | 65 and Over            | 0                   | -                                         |
|                                | Missing                | 2                   | 1.017%                                    |
| <b>BY DSH PERCENT:</b>         |                        |                     |                                           |
|                                | 0-24                   | 896                 | 0.307%                                    |
|                                | 25-49                  | 1,317               | 0.048%                                    |
|                                | 50-64                  | 142                 | -0.074%                                   |
|                                | 65 and Over            | 100                 | -0.055%                                   |
| <b>BY TEACHING STATUS:</b>     |                        |                     |                                           |
|                                | Non-Teaching           | 1,288               | 0.302%                                    |
|                                | Teaching               | 1,167               | -0.057%                                   |

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The actual FY 2027 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2027 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2026 program year would be used for

the updated impact analysis in the final rule, if the proposals, as previously described, for FY 2027 are not finalized.

#### 8. Effects of Requirements Under the Hospital-Acquired Condition Reduction Program for FY 2027

We present the estimated impact of the FY 2027 Hospital-Acquired

Condition (HAC) Reduction Program on hospitals by hospital characteristic based on previously adopted policies for the program. We are not proposing to add or remove any measures from the HAC Reduction Program in this proposed rule, nor are we proposing any changes to reporting or submission requirements. Table I.G.8.-01 in this

section presents the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores by hospital characteristic. Hospitals' CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure results are based on Medicare fee-for-service (FFS) discharges from July 1, 2022, through June 30, 2024, and version 15.0 of the PSI software. Hospitals' measure results for Centers for Disease Control and Prevention (CDC) Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the CDC's National Healthcare Safety Network (NHSN) for

infections occurring between January 1, 2023, and December 31, 2024. Hospital characteristics are based on the FY 2026 IPPS Proposed Rule Impact File.

Table I.G.8.-01 includes 2,891 non-Maryland hospitals with an estimated FY 2027 Total HAC Score based on the most recently available data at the time of publication of this proposed rule. Maryland hospitals and hospitals without a Total HAC Score are excluded from the table. Actual results for FY 2027 will be determined in the fall of 2026 after a 30-day review and corrections period for hospitals to review their program results. The first column presents a breakdown of each characteristic and the second column indicates the number of hospitals for the respective characteristic.

The third column in Table I.G.8.-01 indicates the estimated number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. For example, with regard to teaching status,

401 hospitals out of 1,620 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 210 out of 959 hospitals with fewer than 100 residents and 100 out of 295 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in Table I.G.8.-01 indicates the estimated proportion of hospitals for each characteristic that would be in the worst performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2027 HAC Reduction Program. For example, 24.8 percent of the 1,620 hospitals characterized as non-teaching hospitals, 21.9 percent of the 959 teaching hospitals with fewer than 100 residents, and 33.9 percent of the 295 teaching hospitals with 100 or more residents would be subject to a payment reduction.

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**Table I.G.8.-01 ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORES FOR THE FY 2027 HAC REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC**

| Hospital Characteristic                                                                    | Number of Hospitals | Number of Hospitals in the Worst-performing Quartile <sup>a</sup> | Percent of Hospitals in the Worst-Performing Quartile <sup>b</sup> |
|--------------------------------------------------------------------------------------------|---------------------|-------------------------------------------------------------------|--------------------------------------------------------------------|
| <b>All Hospitals<sup>c</sup></b>                                                           | <b>2,891</b>        | <b>721</b>                                                        | <b>25</b>                                                          |
| <b>By Geographic Location (n = 2,874)</b>                                                  |                     |                                                                   |                                                                    |
| <b>Urban hospitals</b>                                                                     | <b>2,245</b>        | <b>510</b>                                                        | <b>22.7</b>                                                        |
| 1-99 beds                                                                                  | 562                 | 129                                                               | 23.0                                                               |
| 100-199 beds                                                                               | 645                 | 144                                                               | 22.3                                                               |
| 200-299 beds                                                                               | 396                 | 85                                                                | 21.5                                                               |
| 300-399 beds                                                                               | 271                 | 55                                                                | 20.3                                                               |
| 400-499 beds                                                                               | 118                 | 26                                                                | 22.0                                                               |
| 500 or more beds                                                                           | 253                 | 71                                                                | 28.1                                                               |
| <b>Rural hospitals</b>                                                                     | <b>629</b>          | <b>201</b>                                                        | <b>32.0</b>                                                        |
| 1-49 beds                                                                                  | 276                 | 93                                                                | 33.7                                                               |
| 50-99 beds                                                                                 | 186                 | 59                                                                | 31.7                                                               |
| 100-149 beds                                                                               | 94                  | 23                                                                | 24.5                                                               |
| 150-199 beds                                                                               | 42                  | 12                                                                | 28.6                                                               |
| 200 or more beds                                                                           | 31                  | 14                                                                | 45.2                                                               |
| <b>By Teaching Status<sup>d</sup> (n = 2,874)</b>                                          |                     |                                                                   |                                                                    |
| Non-teaching                                                                               | 1,620               | 401                                                               | 24.8                                                               |
| Fewer than 100 residents                                                                   | 959                 | 210                                                               | 21.9                                                               |
| 100 or more residents                                                                      | 295                 | 100                                                               | 33.9                                                               |
| <b>By Ownership (n = 2,874)</b>                                                            |                     |                                                                   |                                                                    |
| Government                                                                                 | 390                 | 146                                                               | 37.4                                                               |
| Proprietary                                                                                | 655                 | 94                                                                | 14.4                                                               |
| Voluntary                                                                                  | 1,829               | 471                                                               | 25.8                                                               |
| <b>By Safety-Net Status<sup>e</sup> (n = 2,874)</b>                                        |                     |                                                                   |                                                                    |
| Safety-net                                                                                 | 583                 | 162                                                               | 27.8                                                               |
| Non-safety net                                                                             | 2,291               | 549                                                               | 24.0                                                               |
| <b>By Disproportionate Share Hospital (DSH) Patient Percentage<sup>f</sup> (n = 2,874)</b> |                     |                                                                   |                                                                    |
| 0-24                                                                                       | 1,103               | 232                                                               | 21.0                                                               |
| 25-49                                                                                      | 1,465               | 387                                                               | 26.4                                                               |
| 50-64                                                                                      | 164                 | 45                                                                | 27.4                                                               |
| 65 and over                                                                                | 142                 | 47                                                                | 33.1                                                               |
| <b>By Medicare Cost Report (MCR) Percentage (n = 2,872)</b>                                |                     |                                                                   |                                                                    |
| 0-24                                                                                       | 1,455               | 352                                                               | 24.2                                                               |
| 25-49                                                                                      | 1,350               | 339                                                               | 25.1                                                               |
| 50-64                                                                                      | 56                  | 14                                                                | 25.0                                                               |
| 65 and over                                                                                | 11                  | 4                                                                 | 36.4                                                               |
| <b>By Region (n = 2,891)</b>                                                               |                     |                                                                   |                                                                    |
| New England                                                                                | 120                 | 38                                                                | 31.7                                                               |
| Middle Atlantic                                                                            | 318                 | 86                                                                | 27.0                                                               |
| East North Central                                                                         | 456                 | 118                                                               | 25.9                                                               |
| West North Central                                                                         | 227                 | 56                                                                | 24.7                                                               |
| South Atlantic                                                                             | 491                 | 97                                                                | 19.8                                                               |
| East South Central                                                                         | 248                 | 83                                                                | 33.5                                                               |
| West South Central                                                                         | 438                 | 86                                                                | 19.6                                                               |
| Mountain                                                                                   | 219                 | 45                                                                | 20.5                                                               |
| Pacific                                                                                    | 374                 | 112                                                               | 29.9                                                               |

Source: FY 2027 HAC Reduction Program estimated proposed rule results are based on CMS PSI 90 data from July 1, 2022, through June 30, 2024, and CDC's NHSN HAI results from January 1, 2023, through December 31, 2024. Hospital Characteristics are based on the FY 2026 IPPS Proposed Rule Impact File.

Note: The total number of hospitals with hospital characteristic data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for geographic location, teaching status, ownership, Safety-net status, and DSH percent (n = 2,874; missing = 17), and MCR percentage (n = 2,872; missing = 19).

<sup>a</sup> This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

<sup>b</sup> This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

<sup>c</sup> The number of non-Maryland hospitals with a Total HAC Score (N = 2,891).

<sup>d</sup> A hospital is considered a teaching hospital if it has an Indirect Medical Education (IME) adjustment factor for Operating PPS (based on the TCHOP variable in the IPPS Impact File) greater than zero.

<sup>e</sup> A hospital is considered a safety-net hospital if it is in the top quintile for DSH percent.

<sup>f</sup> The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

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#### 9. Implementation of the Rural Community Hospital Demonstration (RCHD) Program in FY 2027

In section V.L.2 of the preamble of this proposed rule for FY 2027, we discussed our general budget neutrality methodology for section 410A of Public Law 108173, as amended by sections 3123 and 10313 of Public Law 111-148, by section 15003 of Public Law 114-255, and most recently, by section 128 of Public Law 116-260, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 128 of Public Law 116-260 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 15-year extension period (that is, for an additional 5 years beyond the previous extension period). In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019.

Section 410A(c)(2) of Public Law 108-173, as amended, requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality). To ensure budget neutrality, we propose to continue with the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration and then adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. This proposed methodology applies budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented but does not identify the range across

which aggregate payments must be held equal.

For this proposed rule, we are not yet able to finalize the estimated FY 2027 costs of the demonstration at this time, based on available “as submitted” cost reports to apply the budget neutrality offset to the national IPPS rates as we have done in previous years.

In previous years, we have also incorporated a second component into the budget neutrality offset amounts identified in the IPPS/LTCH PPS final rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier given year differed from the estimated costs for the demonstration set forth in the IPPS/LTCH PPS final rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2018 through 2020 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS/LTCH PPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 128 of Public Law 116-260, we propose to continue with this general procedure. As stated, for the FY2027 proposed rule, we are not yet able to finalize the estimated FY 2027 costs of the demonstration. Therefore, we are not proposing to apply a budget neutrality offset for the FY 2027 IPPS/LTCH PPS proposed rule. Instead, we are proposing to apply both the FY 2027 and FY 2028 estimated costs of the demonstration into the budget neutrality offset to national IPPS rates in the FY 2028 IPPS/LTCH PPS proposed rule. Consistent with our methods in previous years, these estimates will also include the difference between estimated costs and actual costs for the demonstration for FY 2021 and FY 2022 in the budget offset amount. We invite public comments.

#### 10. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VII.C.2 of the preamble of this proposed rule we discuss the implementation of the FCHIP Demonstration, which was authorized under section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275), as amended by section 3126 of the Affordable Care Act of 2010 (Pub. L. 114-158), and most recently re-authorized and extended by the Consolidated Appropriations Act of 2021 (Pub. L. 116-260). The legislation authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries in certain rural areas. The FCHIP demonstration initial period was conducted in 10 critical access hospitals (CAHs) from August 1, 2016, to July 31, 2019, and the demonstration “extension period” began on January 1, 2022, to run through June 30, 2027. Section 123(g)(1)(B) of Public Law 110-275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Budget neutrality estimates for the demonstration described in the preamble of this proposed rule are based on the demonstration extension period.

As described in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), CMS waived certain Medicare rules for CAHs participating in the demonstration extension period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. As we explained in the FY 2026

IPPS/LTCH PPS final rule (90 FR 36971 through 36975), section 129 of Public Law 116–260, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, five elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing the three intervention services.

As explained in the FY 2026 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration extension period of performance in the FY 2026 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

In the FY 2026 IPPS/LTCH PPS final rule, we adopted the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period is not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration extension period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were

not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2026 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2026 IPPS/LTCH PPS final rule, we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. As we explained in the FY 2026 IPPS/LTCH PPS final rule, we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented and does not identify the range across which aggregate payments must be held equal.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS concluded that the initial period of the FCHIP Demonstration had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration. As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. In the FY 2026 IPPS/LTCH PPS final rule, we finalized a policy to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to be used for the demonstration extension period. As stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during the initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/

or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. Therefore, we are not proposing to apply a budget neutrality payment offset to payments to CAHs in FY 2027. This policy will have no impact for any national payment system for FY 2027.

#### 11. Proposed Effects of the Transforming Episode Accountability Model (TEAM)

In section X.A. of the preamble of this proposed rule, we discuss testing the mandatory episode-based payment model titled the Transforming Episode Accountability Model (TEAM) under the authority of the CMS Center for Medicare and Medicaid Innovation (CMS Innovation Center). Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. The intent of TEAM is to improve beneficiary care through financial accountability for episode categories that begin with one of the following procedures: coronary artery bypass graft, lower extremity joint replacement, major bowel procedure, surgical hip/femur fracture treatment, and spinal fusion. TEAM will test whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate that TEAM will benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare fee-for-service (FFS) payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode.

As finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), with subsequent updates made in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536), TEAM is mandatory for acute care hospitals located within mandatory CBSAs and includes acute care hospitals that were eligible for voluntary opt-in participation.<sup>6</sup> TEAM began on

<sup>6</sup> Acute care hospitals that participate in the BPCI Advanced or the CJR model, that are not located in a mandatory CBSA selected for TEAM participation, and continue to participate in BPCI Advanced or CJR until the last day of the last performance period or last performance year of the respective model, were eligible to voluntarily opt into TEAM.

January 1, 2026, and will end on December 31, 2030. Payment approaches that hold providers accountable for episode cost and performance can potentially create incentives for the implementation and coordination of care redesign between participants and other providers and suppliers such as physicians and post-acute care providers. We anticipate TEAM will enable hospitals to consider the most appropriate strategies for care redesign, including (1) increasing post-hospitalization follow-up and medical management for patients; (2) coordinating care across the inpatient and post-acute care spectrum; (3) conducting appropriate discharge planning; (4) improving adherence to treatment or drug regimens; (5) reducing readmissions and complications during the post-discharge period; (6) managing chronic diseases and conditions that may be related to the episodes; (7) choosing the most appropriate post-acute care setting; and (8) coordinating between providers and suppliers such as hospitals, physicians, and post-acute care providers.

Under TEAM, TEAM participants continue to bill Medicare under the traditional FFS system for items and services furnished to Medicare FFS beneficiaries. The TEAM participant may receive a reconciliation payment from CMS if Medicare FFS expenditures for a performance year are less than the reconciliation target price, subject to a quality adjustment. TEAM does not have downside risk for Track 1, meaning TEAM participants will only be accountable for performance year spending below their reconciliation target price, subject to a quality adjustment, that would result in a reconciliation payment amount. For Track 2 and Track 3, TEAM will be a two-sided risk model that requires TEAM participants to be accountable for performance year spending above or below their reconciliation target price, subject to a quality adjustment, that would result in a reconciliation payment amount or a repayment amount.

#### a. Effects on the Medicare Program

TEAM is a mandatory episode-based payment model which will have a direct effect on the Medicare program because TEAM participants are incentivized to reduce Medicare spending. Additionally, TEAM participants could receive a reconciliation payment amount from CMS or have to pay CMS a repayment amount based on their spending and quality performance. In the FY 2026 IPPS/LTCH PPS final rule (90 FR 37271), we estimated and

projected financial impacts of TEAM over the course of the five-year model test. We estimated that on net, that CMS will pay TEAM participants \$381 million and TEAM participants will pay CMS \$469 million, and that TEAM will save the Medicare program approximately \$368 million over the 5 performance years (2026 through 2030).

In this proposed rule, we are proposing several policies and soliciting comments on two Requests for Information (RFIs). We believe the policies that are being proposed would not have a material impact on the Medicare savings estimate. For example, we anticipate that our proposal to include the updated spinal fusion MS-DRGs would help maintain episode volume and spending, and we do not anticipate that updating the quality measure time periods would have a significant effect on Medicare spending or savings. Additionally, the proposals that affect the pricing methodology, such as changes to the construction of the normalization factor and adding update factors to capture current payment system changes, aim to improve the accuracy of target prices but we do not anticipate they would result in dramatic shifts to the Medicare savings estimate. We note that certain policy considerations in the RFIs, such as allowing additional voluntary participation for certain hospitals or adding ASC episodes to TEAM would impact the Medicare savings estimate. Generally, Medicare savings estimates are based on the proposed policies to reflect the potential financial implications of the proposals and are not generally updated based on policies from RFIs. Therefore, TEAM's financial impact to the Medicare program remains unchanged from the FY 2026 IPPS/LTCH PPS final rule.

#### b. Effects on Medicare Beneficiaries

We believe the refinements to TEAM proposed in this proposed rule would not materially alter the potential effects of the model on beneficiaries that we had initially indicated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 70028). We believe the majority of the changes would not alter the effects of the model on beneficiaries because the changes predominantly alter how hospitals interact with the model, rather than how beneficiaries receive care. However, we believe any changes proposed that may have a direct effect on TEAM beneficiaries are positive. In section X.A.2.a.(2) of the preamble of this proposed rule, we proposed the policy to include new spinal fusion episode categories MS-DRGs with the belief that doing so would continue to

capture Medicare beneficiaries in TEAM so they could benefit from improved care transitions and quality of care.

We welcome public comments on the impact of TEAM on Medicare beneficiaries.

#### 12. Proposed Effects of the Comprehensive Care for Joint Replacement Expansion (CJR-X) Model

In section X.C. of this proposed rule, we are proposing to expand the CJR Model, with the expanded model referred to as CJR-X. CJR-X would be a mandatory episode-based payment model under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center). Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. We believe the CJR-X model would further the mission of the Innovation Center to pay for value rather than for volume because it holds CJR-X participants accountable for the cost and quality of care for Medicare beneficiaries during a lower extremity joint replacement (LEJR) episode and promotes alignment across all health care providers and suppliers during the episode of care. In the CJR-X model, the acute care hospital where the anchor hospitalization or anchor procedure occurs would be held accountable for spending during the episode. CJR-X participants would be afforded the opportunity to earn performance-based payments by appropriately reducing expenditures and meeting certain quality metrics. CJR-X participants would also gain access to claims data, pursuant to a request and data sharing agreement, to better understand CJR-X beneficiaries' post-acute care needs and associated spending. Payment approaches that reward providers that assume financial and performance accountability for a particular episode of care create incentives for the implementation and coordination of care redesign between hospitals and other providers and suppliers. Given evidence from the CJR Model, we anticipate CJR-X would continue to reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

It is important to note that CJR-X may have effects beyond the effects to the Medicare program or to Medicare beneficiaries. Since CJR-X would be expanded nationally, except to hospitals excluded in section X.C.2.b.(2)(i). of this proposed rule, we anticipate there may

be spillover effects in the non-Medicare market, or even in the Medicare market in other areas as a result of this model. Changes in Medicare payment policy often have substantial implications for non-Medicare payers. As an example, non-Medicare patients may benefit if CJR-X participants introduce system wide changes that improve the coordination and quality of health care. Other payers may also be developing episode payment models and may align their payment structures with CMS. While there is uncertainty on how much spillover effect will occur with respect to CJR-X, we generally anticipate the effect to be positive given a growing body of evidence.<sup>567 568</sup>

A. Effects on the Medicare Program

CJR-X would be a mandatory episode-based payment model that would have a direct effect on the Medicare program because CJR-X participants would be incentivized to reduce Medicare spending by aiming to have episode expenditures come under the reconciliation target price. CJR-X participants would be subject to two-

sided financial risk, therefore CJR-X participants could receive a reconciliation payment amount from CMS or have to pay CMS a repayment amount based on their spending and quality performance. Financial safeguards have been proposed to ensure outlier high-cost episode spending is capped, stop-gain and stop-loss limits would be applied to prevent extreme reconciliation amounts or repayment amounts, and hospitals meeting the low volume threshold are not held accountable for episodes where there is insufficient volume to spread risk or have opportunities for savings.

Table K-CL-01 shows the projected financial impacts of CJR-X over a 5-year period, with estimated savings to Medicare in each performance year. For the first performance year (October 1, 2027–September 30, 2028), we project CJR-X would generate \$128 million in Medicare savings. Estimated savings increase to \$132 million in performance year 2 and \$136 million in performance year 3. In performance years 4 and 5, projected savings rise to \$159 million and \$170 million, respectively.

We expect episode spending would increase in performance years 4 and 5 due to the conclusion of TEAM and the transition of those hospitals into CJR-X. Although these years reflect higher episode spending and expanded hospital participation, the overall estimated savings impact moderates slightly because a greater proportion of safety net hospitals previously participating in TEAM are included.

Across the five-year period, we project CMS would pay \$1.429 billion to CJR-X participants, while we project CJR-X participants would repay \$1.813 billion to CMS. Combined with expected savings from the assumed 1 percent behavior change from CJR-X participants, which affects both episode spending and reconciliation payments, CJR-X will result in estimated net Medicare savings of approximately \$725 million. We note these projections represent a portion of the potential savings to Medicare that CJR-X may produce since the model does not have an end date.

TABLE K-CL-01: PROJECTED FINANCIAL IMPACTS OF CJR-X (IN MILLIONS)

|                                | Performance Year 1 | Performance Year 2 | Performance Year 3 | Performance Year 4 | Performance Year 5 |
|--------------------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| CJR-X Episode Spending         | \$7,908            | \$8,145            | \$8,365            | \$11,320           | \$12,569           |
| (-) Baseline Episode Spending  | \$7,971            | \$8,209            | \$8,431            | \$11,393           | \$12,645           |
| (+) Reconciliation Amounts*    |                    |                    |                    |                    |                    |
| Reconciliation Payment Amounts | \$239              | \$246              | \$253              | \$329              | \$362              |
| Repayment Amounts              | -\$305             | -\$314             | -\$323             | -\$415             | -\$456             |
| Total Impact                   | -\$128             | -\$132             | -\$136             | -\$159             | -\$170             |
| Impact as % of Baseline        | -1.6%              | -1.6%              | -1.6%              | -1.4%              | -1.3%              |

\* Reconciliation payments and repayments are attributed to the performance year, not the year the payments occur.

(1) Assumptions

Baseline episode spending is projected using 2024 actual spending trended forward for changes in price and Medicare enrollment. We assume price updates would be consistent with projections for payment increases to hospital payments included in the 2025 Trustees Report.<sup>569</sup> We also assume enrollment projections would be consistent with the report. There were no changes to 2024 volume and intensity applied in our projections, as these trends have historically been

negative but have begun to level off. These assumptions have no bearing on savings percentage impacts, only the baseline spending levels.

We also note that baseline spending includes a small impact assumption to account for previous CJR participants increasing spending as a result of not participating in a bundled payment model anymore. We assume about half of the savings from the most recent CJR Model evaluation report (3.4 percent) comes back as a cost to Medicare because they didn't sustain their

episode spending reductions given the lapse of participation in an episode-based payment model from the end of CJR to the start of CJR-X.<sup>570</sup> We note mandatory CJR model participants comprise about 12 percent of episode spending.

CJR-X excludes TEAM participants and since TEAM ends in 2030, TEAM participants are assumed to enter CJR-X in 2031. However, since TEAM uses calendar years for performance, 2031 only includes 3 quarters of TEAM participant spending. We expect TEAM

<sup>567</sup> Navathe, A.S., Liao, J.M., Linn, K.A., Zhang, Y., Mishra, A., Wang, R., Dinh, C.T., Zhu, J., Cousins, D. S., Lindner, J., & Emanuel, E.J. (2020). Spillover effects of Medicare's voluntary bundled payments for joint replacement surgery to patients insured by commercial health plans. *Annals of Internal*

*Medicine*, 174(2), 200–208. <https://doi.org/10.7326/m19-3792>.  
<sup>568</sup> Kim, N., & Jacobson, M. (2025). The spillover effects of Medicare's comprehensive care for joint replacement (CJR) model in California. *PLoS ONE*, 20(4), e0319582. <https://doi.org/10.1371/journal.pone.0319582>.

<sup>569</sup> <https://www.cms.gov/oact/tr/2025>  
<sup>570</sup> Comprehensive Care for Joint Replacement Model—Seventh Annual Report: <https://www.cms.gov/priorities/innovation/data-and-reports/2025/cjr-py7-annual-report>.

participants would not reduce episode spending when they enter the CJR–X in 2031 because their savings are part of CJR–X's baseline. The baseline already assumes that spending was reduced by 1 percent in 2026, consistent with what was estimated for the Medicare savings estimate for TEAM. We also expect TEAM participants to have more spending capped when the stop loss limits are applied. As demonstrated in Table K–CL–01, overall estimated CJR–X model savings impacts as a percentage of baseline spending are reduced when TEAM participants enter the CJR–X model.

We also assume that CJR–X participants would reduce episode spending by 1 percent in the first year of the model and maintain that

reduction going forward. Comparing this assumption to CJR experience, our savings assumption is lower due to the unbiased selection of CJR hospitals (average episode spending for CJR hospitals was much greater than average) and perhaps less potential for similar spending reductions from less costly providers. Further, post-acute care has steadily decreased over time for LEJR procedures, and there may be less opportunity for future decreases in episode spending. This assumption was sensitivity tested in and displayed in Table K–CL–02.

We also note the assumed quality adjustment distribution is based on simulations provided by internal analysis and the average quality adjusted discount is 1.3 percent. Lastly,

the financial impacts assume that the retrospective trend adjustment isn't capped, meaning the difference between prospective trend and retrospective trend are less than 3 percent in magnitude.

## (2) Sensitivity Analysis

We also performed a sensitivity analysis to assess various intervention effects on CJR–X. Overall financial impacts are sensitive to the intervention effect CJR–X would have on participating hospitals' episode spending. Table K–CL–02 includes financial impacts at various intervention effect assumptions (note that negative values indicate savings).

**TABLE K-CL-02: CJR-X SENSITIVITY ANALYSIS AT DIFFERENT INTERVENTION EFFECTS**

| Intervention effect | FY 2028 | FY 2029 | FY 2030 | FY 2031 | FY 2032 |
|---------------------|---------|---------|---------|---------|---------|
| -3.0%               | -2.9%   | -2.9%   | -2.9%   | -2.6%   | -2.6%   |
| -1.0%               | -1.6%   | -1.6%   | -1.6%   | -1.4%   | -1.3%   |
| 0.0%                | -1.0%   | -1.0%   | -1.0%   | -0.8%   | -0.7%   |

Reductions in episode spending lead to lower target prices, however costs from stop loss limits increase as targets prices become more aggressive, since more episode spending is capped. For this reason, overall CJR–X savings does not increase at the same rate as episode spending reductions.

### *B. Effects on Medicare Beneficiaries*

CJR–X may benefit beneficiaries receiving lower extremity joint replacements because the model is intended to improve the coordination and transition of care, invest in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivize higher value care across the inpatient and post-acute care spectrum spanning the episode of care. We believe the model has a patient-centered focus such that healthcare delivery and communication with the patient and or patient caregivers is based on the needs of the beneficiary, thus benefitting the beneficiary community.

We have proposed several quality of care and patient experience measures to assess hospital quality performance in CJR–X with the intent that it will encourage the provider community to focus on and deliver improved quality care for the Medicare beneficiary. We are proposing the adoption and public reporting of five quality measures, as

discussed in section X.C.2.e of this proposed rule, for CJR–X. Those measures include two complications measures, two patient experience survey measures, and one patient reported outcome measure. We propose to use these measures to ensure CJR–X participants are continually measured on the quality of their care and to also monitor for beneficiary safety. Additionally, CJR–X participants must meet the proposed quality performance standards to qualify to receive a reconciliation payment, as discussed in section X.C.2.f.(5).(f) of this proposed rule. The accountability of CJR–X participants for both quality and cost of care provided for Medicare beneficiaries with an LEJR episode provides the hospitals with incentives to improve the health and well-being of the Medicare beneficiaries they treat.

Additionally, the model does not affect the beneficiary's freedom of choice to obtain health services from any individual or organization qualified to participate in the Medicare program guaranteed under section 1802 of the Act. As proposed under CJR–X, eligible beneficiaries who choose to receive services from a CJR–X participant would not have the option to opt out of inclusion in the model. Although the proposed model allows CJR–X participants to enter into financial arrangements with certain other

providers and these hospitals may recommend those providers to the beneficiary, hospitals may not prevent or restrict beneficiaries to any list of preferred or recommended providers.

Many controls exist under Medicare to ensure beneficiary access and quality and in addition we have proposed to monitor hospitals and, if necessary, to audit CJR–X participants if claims analysis indicates an inappropriate change in delivered services. As described in section X.C.2.f.(5)(i) of this proposed rule, given that CJR–X participants would receive a reconciliation payment when they are able to spend below the reconciliation target price and meet quality thresholds, they could have an incentive to avoid complex, high cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from CJR–X participants—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. Furthermore, we also proposed to require providers to supply beneficiaries with written information regarding the design and implications of this model as well as their rights under Medicare, including their right to use their provider of choice.

We have proposed to implement several safeguards to ensure that Medicare beneficiaries do not experience a delay in services. We believe that the longer the episode duration, the lower the risk of delaying care beyond the episode duration, and we believe that a 90-day episode is sufficiently long to minimize the risk that any lower extremity joint replacement related care will be delayed beyond the end of the episode. Moreover, we have proposed as part of the pricing methodology, as described in section X.C.2.f.(5).(h), of this proposed rule that certain outlier costs post-episode payments occurring in the 30-day window subsequent to the end of the 90-day episode will be counted as an adjustment against the reconciliation payment or repayment amount. Importantly, approaches to saving costs will include taking steps that facilitate patient recovery, that shorten recovery duration, and that minimize post-operative problems that might lead to readmissions. Thus, the model itself rewards better patient care.

We welcome public comments on the impact of CJR-X on Medicare beneficiaries.

### 13. Effects of the Proposals Regarding Acquisition Costs, Reasonable Costs, and Other Cost-Related Policies

#### a. Effects of the Proposal To Reconcile Non-Renal Organ Acquisition Costs for Independent Organ Procurement Organizations and Histocompatibility Laboratories

In section X.D.1. of the preamble of this proposed rule, we are proposing to reconcile non-renal organ acquisition costs for independent organ procurement organizations (IOPOs) and histocompatibility laboratories (HCLs), and to require the Medicare administrative contractor (MAC) to establish, adjust if necessary, and publish non-renal standard acquisition charges (SACs) and non-renal testing rates. We are proposing a 1-year delay in implementation, to allow IOPOs and HCLs time to prepare for increased reporting that would be necessary. We estimate this proposal would result in an annual cost savings to the Medicare trust fund of \$0 in FY 2027 due to the proposed 1-year delay in implementation, \$100 million in FY 2028, \$500 million over 5 years from FYs 2027 to 2031, and \$1,280 million over 10 years from FY 2027 to FY 2036. The Office of the Actuary estimated these savings on a cash basis using 2024 Medicare cost report data for IOPOs, comparing total revenue to total organ acquisition costs, by organ type. We do

not have the required data to estimate the impact on HCLs. In accordance with 42 CFR 413.20(a), CMS follows standardized definitions, accounting, statistics, and reporting practices that are widely accepted in the healthcare industry. Changes in these practices and systems are not required to determine costs payable under the principles of reimbursement.

The methods of determining costs payable under Medicare involve making use of data available from the institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services. Burden hours for each OPO/HCL are the estimated time required (number of hours) to complete ongoing data gathering and recordkeeping tasks, search existing data resources, review instructions, and complete the OMB number 0938-0102, Form CMS-216-94. Currently there are 94 Medicare certified OPOs/HCLs that file Form CMS-216-94 annually. The current estimated average burden per OPO/HCL is 45 hours (30 hours for recordkeeping and 15 hours for reporting). For this proposal, we do not estimate additional recordkeeping burden but estimate an average additional reporting burden of 10 hours per OPO/HCL and an estimated additional cost of \$785.40 per OPO/HCL. The most recent median hourly wage data is available from the Bureau of Labor Statistics using their national table (available at <https://www.bls.gov/oes/tables.htm>). The median hourly wage for Category 13-2011 (accounting and audit professionals) is \$39.27. We added 100% of the median hourly wage to account for fringe benefits and overhead costs, which calculates to \$78.54 (\$39.27 + \$39.27) and multiplied it by 10 hours, to determine the additional annual reporting costs per OPO/HCL to be \$785.40 (\$78.54 × 10 hours). We recognize this average reporting burden varies depending on the OPO/HCL's size and complexity. Because there are 94 OPOs and HCLs, the total reporting burden cost would be \$73,828 (94 × \$785.40). In section XII.B.10 of this proposed rule (the Collection of Information section), we invite public comment on the hours estimate as well as the staffing requirements utilized to compile and complete the Medicare cost report. Because we proposed a 1-year delay, if our proposals were to be finalized, these estimated reporting burden costs would not occur until FY 2028.

#### b. Effects of the Reasonable Cost Proposals

In section X.D.2. of the preamble of this proposed rule, we are proposing to change certain existing policy and proposing to codify certain longstanding Medicare reasonable cost reimbursement policies, applicable to all providers reimbursed for all or for some of their services on a reasonable cost basis. We believe these proposals would not result in additional costs to the Medicare program and there would be no increased burden placed upon providers. Additionally, we believe our proposals would alleviate burden on providers by providing more clarity as to certain cost reporting policies. We believe these proposals may result in cost savings to the Medicare program due to increased payment accuracy, but we do not have sufficient data to estimate an amount.

#### c. Effects of the Proposal To Codify Cost Allocation Policy

In section X.D.3. of the preamble of this proposed rule, we are proposing to codify cost allocation principles. This proposal is applicable to all providers. We believe there would be no additional costs to the Medicare program resulting from these proposals. However, we believe these proposals may result in a cost savings to the Medicare program due to increased payment accuracy, although we do not have sufficient data to estimate an amount. We believe these proposals would not increase burden to providers because providers are already required to follow the current cost reporting instructions that we are proposing to codify to properly allocate overhead costs.

#### d. Effects of the Proposal for Discretionary Administrator Review of CMS Reviewing Official Determinations With Respect to Appeals Under § 413.420(g) for Independent Organ Procurement Organizations and Histocompatibility Laboratories

In section X.D.4. of the preamble of this proposed rule, we are proposing to codify the discretionary Administrator review of CMS reviewing official determinations with respect to appeals under § 413.420(g) for IOPOs and HCLs. We believe there would be no additional costs to the Medicare program and no increased burden placed upon providers as a result of our proposal.

#### e. Effects of the Proposed Technical Corrections and Clarifications of §§ 412.116(c) and 413.404(b)(3)(ii)(A) and (C)

In section X.D.5. of the preamble of this proposed rule, we are proposing

technical corrections or clarifications to regulation text at §§ 412.116(c) and 413.404(b)(3)(ii)(A) and (C). These proposed clarifications and corrections would not create any additional costs to the Medicare program or increased burden upon providers.

#### *H. Effects on Hospitals and Hospital Units Excluded From the IPPS*

As of January 2026, there were 95 children's hospitals, 11 cancer hospitals, 6 short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, 1 extended neoplastic disease care hospital, and 8 RNHCs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCs are paid under § 413.40.) Among the remaining providers, the rehabilitation hospitals and units, and the LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and the psychiatric hospitals and units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this proposed rule. The impacts of the changes on LTCHs are discussed in section I.J. of the appendix of this proposed rule.

For the children's hospitals, cancer hospitals, short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCs, the update of the rate-of-increase limit (or target amount) is the estimated proposed FY 2027 percentage increase in the 2023-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's fourth quarter 2025 forecast of the 2023-based IPPS market basket increase, we are estimating the FY 2027 update to be 3.2 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section VI.B. of the preamble of this proposed rule. Section 1886(b)(3)(B)(xi)(I) of the Act requires a productivity adjustment (0.8 percentage point reduction proposed for FY 2027), resulting in a proposed 2.4 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section VI.B. of the preamble of this proposed rule. Children's hospitals, cancer hospitals, short term acute care hospitals located in the Virgin Islands,

Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under section 1886(b)(3)(B)(xi)(I) of the Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the 2023-based IPPS operating market basket for FY 2027, currently estimated at 3.2 percent.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

#### *I. Effects of Changes in the Capital IPPS*

##### *1. General Considerations*

For the impact analysis presented in this section of this proposed rule, we used data from the December 2025 update of the FY 2025 MedPAR file and the December 2025 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2025 update of the most recently available hospital cost report data to categorize hospitals. Our analysis has several qualifications and uses the best data available, as described later in this section of this proposed rule.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon

various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2025 update of the FY 2025 MedPAR file, we simulated payments under the capital IPPS for FY 2026 and the proposed payments for FY 2027 for a comparison of total payments per case. Short-term, acute care hospitals that are not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2027 is as follows:

$$(\text{Standard Federal rate}) \times (\text{DRG weight}) \times (\text{GAF}) \times (\text{COLA for hospitals located in Alaska and Hawaii}) \times (1 + \text{DSH adjustment factor} + \text{IME adjustment factor, if applicable}).$$

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the geographic adjustment factor (GAF) and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this proposed rule, the update to the capital Federal rate is 3.1 percent for FY 2027.

- In addition to the proposed FY 2027 update factor, the proposed FY 2027 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 1.0139, a proposed budget neutrality factor for the 5-percent cap on wage index decreases policy and the proposed continuation of the transition for the discontinuation of the low wage index hospital policy of 0.9913, and a proposed outlier adjustment factor of 0.9642.



## 2. Results

We used the payment simulation model previously described in section I.I. of the Appendix of this proposed rule to estimate the potential impact of the changes for FY 2027 on total capital payments per case, using a universe of 3,013 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the December 2025 update of the FY 2025 MedPAR file, the December 2025 update to the PSF, and the most recent available cost report data from the December 2025 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2026 and estimated proposed total payments per case for FY 2027 based on the proposed FY 2027 payment policies. Column 2 shows estimates of payments per case under our model for FY 2026. Column 3 shows estimates of proposed payments per case under our model for FY 2027. Column 4 shows the total proposed percentage change in payments from FY 2026 to FY 2027. The change represented in Column 4 includes the 3.1 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2027 are expected to increase 2.3 percent compared to capital payments per case in FY 2026. This expected increase is primarily due to the proposed 3.1 percent update to the capital Federal rate being partially offset by a projected decrease in capital outlier

payments. In general, regional variations in estimated capital payments per case in FY 2027 as compared to capital payments per case in FY 2026 are primarily due to the proposed changes in GAFs, and are generally consistent with the projected changes in payments due to the proposed changes in the wage index (and proposed policies affecting the wage index), as shown in Table I in section I.F. of this proposed rule.

The net impact of these changes is an estimated 2.3 percent increase in capital payments per case from FY 2026 to FY 2027 for all hospitals (as shown in Table III). The geographic comparison shows that, on average, hospitals in both urban and rural classifications would experience an increase in capital IPPS payments per case in FY 2027 as compared to FY 2026. Capital IPPS payments per case would increase by an estimated 2.3 percent for hospitals in urban areas and 2.6 percent for rural areas from FY 2026 to FY 2027. The primary factor contributing to the difference in the projected increase in capital IPPS payments per case for rural hospitals as compared to urban hospitals is the estimated increase in capital payments to rural hospitals due to the effect of proposed changes in the GAFs.

The comparisons by region show that the change in capital payments per case from FY 2026 to FY 2027 for urban areas range from a 0.7 percent increase for the West South Central urban region to a 4.7 percent increase for the New England urban region. Meanwhile, the change in capital payments per case from FY 2026 to FY 2027 for rural areas range from a 0.4 percent increase for the Mountain rural region to a 6.4 percent increase for the New England rural region. Capital

IPPS payments per case for hospitals located in Puerto Rico are projected to decrease by 0.3 percent. These regional differences are primarily due to the proposed changes in the GAFs.

The comparison by hospital type of ownership (Voluntary, Proprietary, and Government) shows that voluntary hospitals are expected to experience an increase in capital payments per case from FY 2026 to FY 2027 of 2.3 percent. Proprietary hospitals are expected to experience an increase in capital payments per case from FY 2026 to FY 2027 of 1.5 percent. Government hospitals are expected to experience an increase in capital payments per case from FY 2026 to FY 2027 of 2.3 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2027. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2027, we show the proposed average capital payments per case for reclassified hospitals for FY 2027. Urban reclassified hospitals are expected to experience an increase in capital payments per case of 2.4 percent; urban non-reclassified hospitals are expected to experience an increase in capital payments of 2.1 percent. Rural reclassified hospitals are expected to experience an increase in capital payments per case of 2.7 percent; rural non-reclassified hospitals are expected to experience an increase in capital payments per case of 2.5 percent.

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TABLE III.-- COMPARISON OF TOTAL PAYMENTS PER CASE

| <b>FY 2026 PAYMENTS COMPARED TO FY 2027 PAYMENTS</b> | <b>Number of Hospitals</b> | <b>Average FY 2026 Payments/Case</b> | <b>Proposed Average FY 2027 Payments/Case</b> | <b>Change</b> |
|------------------------------------------------------|----------------------------|--------------------------------------|-----------------------------------------------|---------------|
| All Hospitals                                        | 3013                       | 1243                                 | 1272                                          | 2.3           |
| <b>By Geographic Location:</b>                       |                            |                                      |                                               |               |
| Urban hospitals                                      | 2357                       | 1278                                 | 1307                                          | 2.3           |
| Rural hospitals                                      | 656                        | 848                                  | 870                                           | 2.6           |
| <b>Bed Size (Urban):</b>                             |                            |                                      |                                               |               |
| 0-99 beds                                            | 639                        | 964                                  | 971                                           | 0.7           |
| 100-199 beds                                         | 673                        | 1063                                 | 1086                                          | 2.2           |
| 200-299 beds                                         | 401                        | 1153                                 | 1177                                          | 2.1           |
| 300-499 beds                                         | 391                        | 1271                                 | 1301                                          | 2.4           |
| 500 or more beds                                     | 251                        | 1531                                 | 1569                                          | 2.5           |
| <b>Bed Size (Rural):</b>                             |                            |                                      |                                               |               |
| 0-49 beds                                            | 316                        | 703                                  | 718                                           | 2.1           |
| 50-99 beds                                           | 175                        | 809                                  | 824                                           | 1.9           |
| 100-149 beds                                         | 95                         | 825                                  | 844                                           | 2.3           |
| 150-199 beds                                         | 41                         | 911                                  | 932                                           | 2.3           |
| 200 or more beds                                     | 29                         | 1037                                 | 1079                                          | 4.1           |
| <b>Urban by Region:</b>                              |                            |                                      |                                               |               |
| New England                                          | 102                        | 1361                                 | 1425                                          | 4.7           |
| Middle Atlantic                                      | 272                        | 1444                                 | 1471                                          | 1.9           |
| East North Central                                   | 364                        | 1184                                 | 1202                                          | 1.5           |
| West North Central                                   | 155                        | 1208                                 | 1246                                          | 3.1           |
| South Atlantic                                       | 393                        | 1135                                 | 1161                                          | 2.3           |
| East South Central                                   | 140                        | 1047                                 | 1083                                          | 3.4           |
| West South Central                                   | 357                        | 1179                                 | 1187                                          | 0.7           |
| Mountain                                             | 177                        | 1267                                 | 1287                                          | 1.6           |
| Pacific                                              | 346                        | 1598                                 | 1641                                          | 2.7           |
| <b>Rural by Region:</b>                              |                            |                                      |                                               |               |
| New England                                          | 19                         | 1110                                 | 1181                                          | 6.4           |
| Middle Atlantic                                      | 47                         | 991                                  | 1010                                          | 1.9           |
| East North Central                                   | 106                        | 836                                  | 849                                           | 1.6           |
| West North Central                                   | 72                         | 862                                  | 880                                           | 2.1           |
| South Atlantic                                       | 109                        | 762                                  | 788                                           | 3.4           |
| East South Central                                   | 122                        | 756                                  | 779                                           | 3.0           |
| West South Central                                   | 117                        | 754                                  | 765                                           | 1.5           |
| Mountain                                             | 40                         | 917                                  | 921                                           | 0.4           |
| Pacific                                              | 24                         | 1075                                 | 1101                                          | 2.4           |
| <b>Puerto Rico:</b>                                  |                            |                                      |                                               |               |
| Puerto Rico Hospitals                                | 51                         | 608                                  | 606                                           | -0.3          |
| <b>By Payment Classification:</b>                    |                            |                                      |                                               |               |
| Urban hospitals                                      | 1528                       | 1160                                 | 1186                                          | 2.2           |
| Rural areas                                          | 1485                       | 1297                                 | 1327                                          | 2.3           |
| <b>Teaching Status:</b>                              |                            |                                      |                                               |               |
| Nonteaching                                          | 1710                       | 1005                                 | 1025                                          | 2.0           |
| Fewer than 100 residents                             | 997                        | 1153                                 | 1180                                          | 2.3           |
| 100 or more residents                                | 306                        | 1672                                 | 1711                                          | 2.3           |
| <b>Urban DSH:</b>                                    |                            |                                      |                                               |               |
| Non-DSH                                              | 355                        | 1071                                 | 1084                                          | 1.2           |
| 100 or more beds                                     | 837                        | 1203                                 | 1232                                          | 2.4           |
| Less than 100 beds                                   | 336                        | 864                                  | 881                                           | 2.0           |
| <b>Rural DSH:</b>                                    |                            |                                      |                                               |               |
| Non-DSH                                              | 114                        | 1156                                 | 1182                                          | 2.2           |
| SCH                                                  | 222                        | 877                                  | 894                                           | 1.9           |
| RRC                                                  | 920                        | 1342                                 | 1373                                          | 2.3           |
| 100 or more beds                                     | 41                         | 1185                                 | 1214                                          | 2.4           |
| Less than 100 beds                                   | 188                        | 719                                  | 735                                           | 2.2           |
| <b>Urban teaching and DSH:</b>                       |                            |                                      |                                               |               |
| Both teaching and DSH                                | 483                        | 1260                                 | 1293                                          | 2.6           |
| Teaching and no DSH                                  | 62                         | 1123                                 | 1149                                          | 2.3           |
| No teaching and DSH                                  | 690                        | 1062                                 | 1085                                          | 2.2           |

| <b>FY 2026 PAYMENTS COMPARED TO FY 2027 PAYMENTS</b>        | <b>Number of Hospitals</b> | <b>Average FY 2026 Payments/Case</b> | <b>Proposed Average FY 2027 Payments/Case</b> | <b>Change</b> |
|-------------------------------------------------------------|----------------------------|--------------------------------------|-----------------------------------------------|---------------|
| No teaching and no DSH                                      | 293                        | 1036                                 | 1040                                          | 0.4           |
| <b>Special Hospital Types:</b>                              |                            |                                      |                                               |               |
| SCH                                                         | 425                        | 997                                  | 1024                                          | 2.7           |
| MDH                                                         | 160                        | 788                                  | 807                                           | 2.4           |
| <b>Type of Ownership:</b>                                   |                            |                                      |                                               |               |
| Voluntary                                                   | 1909                       | 1239                                 | 1268                                          | 2.3           |
| Proprietary                                                 | 693                        | 1162                                 | 1179                                          | 1.5           |
| Government                                                  | 409                        | 1369                                 | 1401                                          | 2.3           |
| <b>Medicare Utilization as a Percent of Inpatient Days:</b> |                            |                                      |                                               |               |
| 0-25                                                        | 1666                       | 1294                                 | 1322                                          | 2.2           |
| 25-50                                                       | 1272                       | 1186                                 | 1214                                          | 2.4           |
| 50-65                                                       | 42                         | 1163                                 | 1195                                          | 2.8           |
| Over 65                                                     | 9                          | 843                                  | 891                                           | 5.7           |
| <b>Medicaid Utilization as a Percent of Inpatient Days:</b> |                            |                                      |                                               |               |
| 0-25                                                        | 2009                       | 1146                                 | 1173                                          | 2.4           |
| 25-50                                                       | 886                        | 1418                                 | 1448                                          | 2.1           |
| 50-65                                                       | 88                         | 1537                                 | 1562                                          | 1.6           |
| Over 65                                                     | 30                         | 1596                                 | 1631                                          | 2.2           |
| <b>FY 2027 Reclassifications:</b>                           |                            |                                      |                                               |               |
| All Reclassified Hospitals                                  | 1195                       | 1312                                 | 1343                                          | 2.4           |
| Non-Reclassified Hospitals                                  | 1818                       | 1134                                 | 1158                                          | 2.1           |
| Urban Hospitals Reclassified                                | 1007                       | 1344                                 | 1376                                          | 2.4           |
| Urban Non-Reclassified Hospitals                            | 1368                       | 1160                                 | 1184                                          | 2.1           |
| Rural Hospitals Reclassified Full Year                      | 276                        | 861                                  | 884                                           | 2.7           |
| Rural Non-Reclassified Hospitals Full Year                  | 362                        | 826                                  | 847                                           | 2.5           |
| All Section 401 Rural Reclassified Hospitals                | 882                        | 1360                                 | 1390                                          | 2.2           |
| Other Reclassified Hospitals (Section 1886(d)(8)(B))        | 53                         | 868                                  | 892                                           | 2.8           |

**BILLING CODE 4120-01-C***J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS***1. Introduction and General Considerations**

In section X. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2027. In the preamble of this proposed rule, we specify the statutory authority for the proposals that are presented, identify the proposed policies for FY 2027, and present rationales for our proposals as well as alternatives that were considered. In this section, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal

payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2).

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS-LTC-DRG relative weight, we make adjustments to account for area wage levels and short stay outliers (SSOs). LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is,

those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate).

In addition, when certain thresholds are met, LTCHs also receive high-cost outlier (HCO) payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

**2. Proposed Updates to Payments for LTCH PPS Standard Federal Payment Rate Cases**

This section details the proposed updates to the LTCH PPS payment rates and related factors that would affect payments for LTCH PPS standard Federal payment rate cases and serve as the basis for the impact analysis presented in this proposed rule.

- As discussed in section V.A.2. of the Addendum to this proposed rule, for FY 2027, we are proposing to establish an LTCH PPS standard Federal payment rate of \$52,177.04 which reflects the proposed 2.4 percent annual update to the LTCH PPS standard Federal payment rate and the proposed budget neutrality factor for updates to the area wage level adjustment of 1.0025505. For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are

proposing to establish an LTCH PPS standard Federal payment rate of \$51,157.95. This proposed LTCH PPS standard Federal payment rate reflects the proposed updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP.

- As discussed in section V.B.3. of the Addendum to this proposed rule, for FY 2027, we are proposing to establish a labor-related share of 73.0 percent for FY 2027, based on the most recent available data (IGI's fourth quarter 2025 forecast) of the relative importance of the labor-related share of operating and capital costs of the 2022-based LTCH market basket.

- As discussed in section V.B.4. of the Addendum to this proposed rule, for FY 2027, we are proposing to update the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2023 which is the same data used for the FY 2027 IPPS wage index).

- As discussed in section V.C. of the Addendum to this proposed rule, for FY 2027, we are proposing to update the COLA factors used to adjust non-labor related costs for LTCHs located in Alaska and Hawaii using the Overseas Cost-of-Living Allowance (OCOLA) data published by the Department of Defense (DOD).

- As discussed in section X.B. of the preamble of this proposed rule, for FY 2027, we are proposing to update the MS–LTC–DRG classifications and MS–LTC–DRG relative weights.

- As discussed in section V.C. of the Addendum to this proposed rule, for FY 2027, we are proposing to maintain the fixed-loss amount for LTCH PPS standard Federal payment rate cases at its FY 2026 level of \$78,936. We estimate this will result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2027 payments for such cases.

### 3. Impact Analysis

#### a. Basis and Methodology of Estimates

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 2027, it is necessary to estimate payments per discharge for FY 2026 using the rates, factors, and the policies established in the FY 2026 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2027 using the proposed rates, factors, and the policies in this proposed rule (as discussed in section X. of the preamble of this

proposed rule and section V. of the Addendum to this proposed rule). The resulting analyses can then be used to compare how our proposed policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

Specifically, to estimate the per discharge payment effects of our proposals on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2026 and proposed FY 2027 payments on a case-by-case basis using historical LTCH claims from the FY 2025 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2025 MedPAR files. We note that in modeling payments for HCO cases, we scaled outlier payments to equal 7.975 percent of total estimated LTCH PPS payments for standard Federal payment rate cases in both FY 2026 and FY 2027.

There are 318 LTCHs included in this impact analysis. We note that, although there are currently approximately 325 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2027 MS–LTC–DRG relative weights (discussed in section X.B.3. of the preamble of this proposed rule). Moreover, in the claims data used for this proposed rule, two of the 325 LTCHs only had claims for site neutral payment rate cases and, therefore, do not affect our impact analysis for LTCH PPS standard Federal payment rate cases presented in Table IV.

Based on the FY 2025 LTCH cases that were used for the analysis in this proposed rule, approximately 7 percent of those cases were classified as site neutral payment rate cases (that is, 7 percent of LTCH cases would not meet the statutory patient-level criteria for exclusion from the site neutral payment rate). Accordingly, based on the FY 2025 LTCH cases that were used for the analysis in this proposed rule, approximately 93 percent of LTCH cases would meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2027 and would be paid based on the LTCH PPS standard Federal payment rate.

In the following section, we present in Table IV our provider impact analysis for the proposed changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among

various classifications of LTCHs, reflecting the estimated “losses” or “gains” from FY 2026 to FY 2027 based on the proposed payment rates and policy changes presented in this proposed rule. We note that our analysis does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the proposed policies in this proposed rule. Consistent with prior years, Table IV only reflects proposed changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

In Table IV, LTCHs are grouped based on characteristics provided in hospital cost report data and PSF data. LTCH groups included the following:

- Location: large urban/other urban/rural.
- Ownership control.
- Census region.
- Bed size.

We include the following columns in Table IV:

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2026 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fifth column shows the estimated FY 2027 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2026 to FY 2027 due to the proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 due to the proposed changes to the area wage level adjustment (that is, the proposed updated hospital wage data and the proposed labor-related share) and the application of the corresponding proposed budget neutrality factor (as

|                                                                                                                                                                                  |                                                                         |                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| discussed in section V.B.6. of the Addendum to this proposed rule). <ul style="list-style-type: none"><li>• The eighth column shows the percentage change in estimated</li></ul> | payments per discharge for LTCH PPS standard Federal payment rate cases | from FY 2026 (Column 4) to FY 2027 (Column 5) due to all changes.<br><b>BILLING CODE 4120-01-P</b> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|

**TABLE IV: IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2027 (ESTIMATED FY 2026 PAYMENTS COMPARED TO ESTIMATED FY 2027 PAYMENTS)**

| LTCH Classification<br>(1) | No. of LTCHS<br>(2) | Number of LTCH<br>PPS Standard<br>Payment Rate<br>Cases<br>(3) | Average FY<br>2026 LTCH<br>PPS Payment<br>Per Standard<br>Payment Rate<br>(4) | Average FY<br>2027 LTCH<br>PPS Payment<br>Per Standard<br>Payment Rate <sup>1</sup><br>(5) | Change Due<br>to Change to<br>the Annual<br>Update to the<br>Standard<br>Federal Rate <sup>2</sup><br>(6) | Percent Change<br>Due to Changes<br>to Area Wage<br>Adjustment with<br>Wage Budget<br>Neutrality <sup>3</sup><br>(7) | Percent<br>Change Due to<br>All Standard<br>Payment Rate<br>Changes <sup>4</sup><br>(8) |
|----------------------------|---------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| ALL PROVIDERS              | 318                 | 41,082                                                         | 58,508                                                                        | 59,857                                                                                     | 2.3                                                                                                       | 0.0                                                                                                                  | 2.3                                                                                     |
| BY LOCATION:               |                     |                                                                |                                                                               |                                                                                            |                                                                                                           |                                                                                                                      |                                                                                         |
| RURAL                      | 16                  | 1,020                                                          | 47,283                                                                        | 48,107                                                                                     | 2.3                                                                                                       | -0.3                                                                                                                 | 1.7                                                                                     |
| URBAN                      | 302                 | 40,062                                                         | 58,794                                                                        | 60,156                                                                                     | 2.3                                                                                                       | 0.0                                                                                                                  | 2.3                                                                                     |
| BY OWNERSHIP TYPE:         |                     |                                                                |                                                                               |                                                                                            |                                                                                                           |                                                                                                                      |                                                                                         |
| VOLUNTARY                  | 52                  | 4,807                                                          | 59,276                                                                        | 60,419                                                                                     | 2.3                                                                                                       | -0.3                                                                                                                 | 1.9                                                                                     |
| PROPRIETARY                | 258                 | 35,759                                                         | 58,163                                                                        | 59,517                                                                                     | 2.3                                                                                                       | 0.0                                                                                                                  | 2.3                                                                                     |
| GOVERNMENT                 | 8                   | 516                                                            | 75,269                                                                        | 78,168                                                                                     | 2.3                                                                                                       | 1.1                                                                                                                  | 3.9                                                                                     |
| BY REGION:                 |                     |                                                                |                                                                               |                                                                                            |                                                                                                           |                                                                                                                      |                                                                                         |
| NEW ENGLAND                | 9                   | 1,278                                                          | 48,989                                                                        | 49,974                                                                                     | 2.3                                                                                                       | 0.4                                                                                                                  | 2.0                                                                                     |
| MIDDLE ATLANTIC            | 20                  | 2,968                                                          | 69,643                                                                        | 72,034                                                                                     | 2.3                                                                                                       | 1.1                                                                                                                  | 3.4                                                                                     |
| SOUTH ATLANTIC             | 60                  | 9,195                                                          | 57,051                                                                        | 58,256                                                                                     | 2.3                                                                                                       | -0.3                                                                                                                 | 2.1                                                                                     |
| EAST NORTH CENTRAL         | 46                  | 4,993                                                          | 61,234                                                                        | 62,350                                                                                     | 2.3                                                                                                       | -0.5                                                                                                                 | 1.8                                                                                     |
| EAST SOUTH CENTRAL         | 32                  | 3,068                                                          | 51,845                                                                        | 52,617                                                                                     | 2.3                                                                                                       | -0.8                                                                                                                 | 1.5                                                                                     |
| WEST NORTH CENTRAL         | 22                  | 2,104                                                          | 53,819                                                                        | 55,105                                                                                     | 2.3                                                                                                       | 0.2                                                                                                                  | 2.4                                                                                     |
| WEST SOUTH CENTRAL         | 81                  | 9,441                                                          | 51,140                                                                        | 52,073                                                                                     | 2.3                                                                                                       | -0.2                                                                                                                 | 1.8                                                                                     |
| MOUNTAIN                   | 25                  | 2,183                                                          | 58,014                                                                        | 59,639                                                                                     | 2.3                                                                                                       | 0.0                                                                                                                  | 2.8                                                                                     |
| PACIFIC                    | 23                  | 5,852                                                          | 72,157                                                                        | 74,372                                                                                     | 2.3                                                                                                       | 0.6                                                                                                                  | 3.1                                                                                     |
| BY BED SIZE:               |                     |                                                                |                                                                               |                                                                                            |                                                                                                           |                                                                                                                      |                                                                                         |
| BEDS: 0-24                 | 31                  | 1,836                                                          | 60,981                                                                        | 62,612                                                                                     | 2.3                                                                                                       | 0.3                                                                                                                  | 2.7                                                                                     |
| BEDS: 25-49                | 152                 | 15,466                                                         | 52,556                                                                        | 53,584                                                                                     | 2.3                                                                                                       | -0.2                                                                                                                 | 2.0                                                                                     |
| BEDS: 50-74                | 74                  | 10,305                                                         | 60,115                                                                        | 61,520                                                                                     | 2.3                                                                                                       | 0.0                                                                                                                  | 2.3                                                                                     |
| BEDS: 75-124               | 42                  | 8,386                                                          | 65,761                                                                        | 67,471                                                                                     | 2.3                                                                                                       | 0.1                                                                                                                  | 2.6                                                                                     |
| BEDS: 125+                 | 19                  | 5,089                                                          | 60,502                                                                        | 62,013                                                                                     | 2.3                                                                                                       | 0.3                                                                                                                  | 2.5                                                                                     |

<sup>1</sup> Estimated FY 2027 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the proposed payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed rule.

<sup>2</sup> Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 due to the proposed annual update to the LTCH PPS standard Federal payment rate.

<sup>3</sup> Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 due to the proposed changes to the area wage level adjustment under § 412.525(c) (that is, the proposed updated hospital wage data and the proposed labor-related share) with budget neutrality.

<sup>4</sup> Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 (shown in Column 4) to FY 2027 (shown in Column 5), due to all of the proposed changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this proposed rule.

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## b. Results

Based on the FY 2025 LTCH cases (from 318 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the proposed LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to increase 2.3 percent, on average, for all LTCHs from FY 2026 to FY 2027, as a result of the proposed payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 2.3 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2027 LTCH PPS payments for LTCH PPS standard Federal payment rate cases (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2026 LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

As stated previously, we are proposing an annual update to the LTCH PPS standard Federal payment rate for FY 2027 of 2.4 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. The estimated change attributable solely to the proposed annual update of 2.4 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.3 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027, on average, for all LTCHs (Column 6). The estimated increase of 2.3 percent shown in Column 6 also includes estimated payments for SSO cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. For all hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases also rounds to approximately 2.3 percent.

## (1) Location

The vast majority of LTCHs are located in urban areas. The impact analysis presented in Table IV shows that the average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 for all LTCHs is 2.3 percent. Urban LTCHs are also projected to experience an increase of 2.3 percent.

Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 2 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. As shown in Table IV, we are projecting a 1.7 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This increase is primarily due to the proposed 2.4 percent annual update to the LTCH PPS standard Federal payment rate for FY 2027 being partially offset by a projected decrease in payments due to the proposed changes to the area wage level adjustment and the proposed changes to the MS-LTC-DRG classifications and relative weights.

## (2) Ownership Control

LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the best available data, approximately 16 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 81 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, proprietary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases of 2.3 percent. Voluntary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 of 1.9 percent. Government owned and operated LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 of 3.9 percent.

## (3) Census Region

The comparisons by region show that the changes in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 are projected to increase from 1.5 percent in the East South Central region to 3.4 percent in the Middle Atlantic region. These

regional variations are primarily due to the changes to the area wage adjustment.

## (4) Bed Size

LTCHs are grouped into five categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; and greater than 125 beds. We project that LTCHs with 0–24 beds will experience the largest increase in payments with 2.7 percent. The remaining bed size categories are projected to experience an increase in payments in the range of 2.0 to 2.6 percent.

## 4. Effect on the Medicare Program

We project that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2027 relative to FY 2026 of approximately 2.3 percent for the 318 LTCHs in our database. We estimate that aggregate FY 2027 LTCH PPS payments to LTCH PPS standard Federal payment rate cases will be approximately \$2.459 billion, as compared to estimated aggregate FY 2026 LTCH PPS payments of approximately \$2.404 billion, resulting in an estimated overall increase in payments of approximately \$55 million.

As we discuss in detail throughout this proposed rule, based on the best available data, we believe that the provisions of this proposed rule relating to the LTCH PPS and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

## 5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this proposed rule, and we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the implementation of the site neutral payment system to have a negative impact on access to or quality of care. As demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

*K. Effects of Proposed Requirements for the Hospital Inpatient Quality Reporting Program*

In sections IX.B. and IX.C. of the preamble of this proposed rule, we discuss the proposed requirements for hospitals reporting quality data under the Hospital Inpatient Quality Reporting Program to receive the full annual percentage increase for the FY 2029 payment determination and subsequent years.

In this proposed rule, we are proposing to adopt three new measures: (1) the Advance Care Planning electronic clinical quality measure (eCQM) beginning with the CY 2028 reporting period/FY 2030 payment determination; (2) the Hospital Harm-Postoperative Venous Thromboembolism (VTE) eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination; (3) the Excess Days in Acute Care After Hospitalization for Diabetes measure beginning with the July 1, 2025 through June 30, 2027 performance period, associated with the FY 2029 payment determination. We are also proposing to adopt five mortality measures for the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination, through the July 1, 2027 through June 30, 2029 performance period, associated with the FY 2031 payment determination: (1) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization measure; (2) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization measure; (3) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure; (4) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization measure; and (5) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery measure. We are also proposing to modify three measures beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination: (1) the Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction measure; (2) the Excess Days in Acute Care after Hospitalization for Heart Failure measure; and (3) the Excess Days in Acute Care after Hospitalization for Pneumonia measure. We are proposing to remove three eCQMs beginning with the CY 2028 reporting period/FY 2030

payment determination: (1) the VTE Prophylaxis eCQM; (2) the Intensive Care Unit VTE Prophylaxis eCQM; and (3) Discharged on Antithrombotic Therapy eCQM. We are also proposing an update to the reporting and submission requirements for the Maternal Morbidity Structural measure beginning with the CY 2026 reporting period/FY 2028 payment determination. Lastly, we are proposing to modify the reporting and submission requirements for eCQMs to require mandatory reporting of the Malnutrition Care Score eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination, and to require mandatory reporting of Hospital Harm eCQMs after 2 years of self-selected reporting beginning with the CY 2028 reporting period/FY 2030 payment determination.

As shown in the summary tables in section XII.B.4.h. of the preamble of this proposed rule, we estimate an increase of 8,133 hours at a cost of \$447,803 in information collection burden associated with the proposed policies compared to the currently approved information collection burden estimates under OMB control number 0938–1022 (expiration date December 31, 2028).

In section IX.B.1. of the preamble of this proposed rule, we are proposing to adopt the Advance Care Planning eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination. Additionally, in sections IX.C.3.b. and IX.C.4. of the preamble of this proposed rule, we are proposing to adopt the Hospital Harm-Postoperative VTE eCQM and subsequently remove the VTE Prophylaxis and Intensive Care Unit VTE Prophylaxis eCQMs beginning with the CY 2028 reporting period/FY 2030 payment determination. While there is no change in information collection burden associated with these proposals because the VTE Prophylaxis and Intensive Care Unit VTE Prophylaxis eCQMs are available for hospitals to self-select to meet eCQM reporting requirements and the proposed Hospital Harm-Postoperative VTE eCQM would also be available for hospitals to self-select, we note that there would be a reduction in administrative burden as the proposals would result in replacing two process eCQMs with a single comprehensive outcome eCQM. We note that Hospital Harm-Postoperative VTE eCQM would become mandatory if the proposal to require Hospital Harm eCQMs after two years of self-selected reporting is finalized, and we have provided estimates for the Collection of Information burden in section XII.B.4.g. in the preamble of this proposed rule.

We note the administrative costs associated with adoption of eCQMs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in hospitals' EHR systems for the eCQMs used in the Hospital Inpatient Quality Reporting Program.

We do not anticipate any additional economic impact beyond those discussed in section XII.B.4. of the preamble of this proposed rule (Collection of Information) for the remaining proposals.

Historically, 100 hospitals, on average, that participate in the Hospital Inpatient Quality Reporting Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years based on review of previous performance.

*L. Effects of Proposed Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program*

In sections IX.B. and IX.D. of the preamble of this proposed rule, we discuss proposed requirements for PPS-Exempt Cancer Hospitals (PCHs) reporting quality data under the PCH Quality Reporting Program. The PCH Quality Reporting Program is authorized under section 1866(k) of the Act. There is no financial impact to Medicare reimbursement if a PCH does not submit data.

We are proposing to adopt two measures beginning with the CY 2028 reporting period/FY 2030 program year: (1) the Advance Care Planning electronic clinical quality measure (eCQM); and (2) the Malnutrition Care Score eCQM. We are also proposing to remove the COVID–19 Vaccination Coverage among Healthcare Personnel measure beginning with the CY 2026 reporting period/FY 2028 program year.

As shown in the summary tables in section XII.B.5. of the preamble of this proposed rule, across all PCHs we estimate an increase of 15 hours at a cost of \$826 in information collection burden associated with the proposed policies compared to the currently approved information collection burden estimates under OMB control number 0938–1175 (expiration date January 31, 2029). We also estimate a decrease of between 88 hours at a savings of \$4,972 and 99 hours at a savings of \$5,801 in information collection burden associated with the finalized policies



compared to the currently approved information collection burden estimates under OMB control number 0920–1317 (expiration date January 31, 2028).

With regard to administrative costs associated with adoption of eCQMs, we believe they are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in PCHs' electronic health record systems for the eCQMs used in the PCH Quality Reporting Program. As discussed in section IX.D.5.b.(1). of this proposed rule, we intend to transition to a fully digital quality measure landscape by transitioning eCQMs to Health Level 7® Fast Healthcare Interoperability Resources® (FHIR®)-based eCQMs to promote interoperability and increase the value of quality measure data.<sup>571 572</sup>

We do not believe removal of the COVID–19 Vaccination Coverage among Healthcare Personnel measure would result in any additional economic impact beyond that discussed in section XII.B.5.c. of the preamble of this proposed rule (Collection of Information).

*M. Proposed Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)*

In section IX.E.3. of the preamble of this proposed rule, we are proposing to remove the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) (HCP COVID–19 Vaccine) measure. We are also proposing, in section IX.E.4. of the preamble of this proposed rule, to remove the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) measure. If these proposals are finalized, both measure

removals will be effective beginning with the FY 2028 LTCH QRP. In section IX.E.6.b. of the preamble of this proposed rule, we are proposing to revise the data submission deadline for LCDS assessment and CDC NHSN data for the LTCH QRP. Finally, in sections IX.E.5. of the preamble of this proposed rule, we seek public comments on future measure concepts for the LTCH QRP.

The effect of these proposals for the LTCH QRP would be an overall decrease in burden for LTCHs participating in the LTCH QRP. As shown in summary table I.M.-01, we estimate a decrease in total annual burden of 4,473 hours and \$207,309.29 for 318 eligible LTCHs associated with our proposed policies. We refer readers to section XII.B.8. of the preamble of this proposed rule, where CMS has provided an estimate of the burden and cost to LTCHs.

**TABLE I.M.-01: ESTIMATED BURDEN ASSOCIATED WITH THE FY 2028 LTCH QRP**

| Requirement                                                           | Per LTCH                      |                       | All LTCHs                     |                       |
|-----------------------------------------------------------------------|-------------------------------|-----------------------|-------------------------------|-----------------------|
|                                                                       | Change in Annual Burden Hours | Change in Annual Cost | Change in Annual Burden Hours | Change in Annual Cost |
| Proposed Removal of the Patient/Resident COVID-19 Measure             | -1.61                         | -\$126.08             | -513                          | -\$40,092.17          |
| Proposed Removal of the HCP COVID-19 Vaccine Measure.                 | -12.00                        | -\$525.84             | -3,960                        | -\$167,217.12         |
| Total estimated change in burden associated with the FY 2028 LTCH QRP | -13.61                        | -\$651.92             | -4,473                        | -\$207,309.29         |

We are seeking comments specific to the estimates.

*N. Effects of Proposed Requirements Regarding the Medicare Promoting Interoperability Program*

In sections IX.B. and IX.F. of the preamble of this proposed rule, we discuss proposed requirements for eligible hospitals and critical access hospitals (CAHs) to report objectives and measures and electronic clinical quality measures (eCQMs) under the Medicare Promoting Interoperability Program.

In this proposed rule, we are proposing to adopt three new measures beginning with the EHR reporting period in CY 2028: (1) the Advance Care Planning eCQM beginning with the CY 2028 reporting period; (2) the Hospital Harm-Postoperative Venous Thromboembolism (VTE) eCQM beginning with the CY 2028 reporting period; and (3) the Unique Device Identifiers for Implantable Medical Devices measure beginning with the EHR reporting period in CY 2027.

Additionally, we are proposing to remove two attestations and five measures: (1) the Office of the National Coordinator for Health Information Technology (ONC) Direct Review Attestation beginning with the EHR reporting period in CY 2026; (2) the optional ONC–Authorized Certification Body (ONC–ACB) Surveillance Attestation beginning with the EHR reporting period in CY 2026; (3) the Support Electronic Referral Loops by Sending Health Information measure beginning with the EHR reporting period in CY 2028; (4) the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure beginning with the EHR reporting period in CY 2028; (5) the Venous Thromboembolism Prophylaxis (VTE) Prophylaxis eCQM beginning with the CY 2028 reporting period; (6) the Intensive Care Unit VTE Prophylaxis eCQM beginning with the CY 2028 reporting period; and (7) the Discharged on Antithrombotic Therapy eCQM beginning with the CY 2028 reporting

period. We are also proposing updates to the Electronic Prior Authorization measure by modifying the ONC certification criteria eligible hospitals and CAHs must use to attest “Yes,” modifying the measure text, and proposing to make the measure an optional bonus measure for the EHR reporting period in CY 2027 and required for the EHR reporting period in CY 2028. Lastly, we are proposing to modify the reporting and submission requirements for the Malnutrition Care Score eCQM beginning with the CY 2028 reporting period and modify the reporting and submission requirements for Hospital Harm eCQMs to require mandatory reporting after 2 years of self-selected reporting beginning with the CY 2028 reporting period.

As discussed in section XII.B.7.i. of the preamble of this proposed rule, we estimate a decrease of 3,886 hours at a cost of \$213,982 in information collection burden associated with our proposed policies and updated burden estimates for the EHR reporting period in CY 2026 and future years compared

<sup>571</sup> For more information on dQMs, visit: <https://ecqi.healthit.gov/dqm/about-dqms>.

<sup>572</sup> FHIR® is the registered trademark of Health Level Seven International (HL7), and its use does not constitute endorsement by HL7.

to our currently approved information collection burden estimates. We refer readers to section XIII.B.7. of the preamble of this proposed rule (Collection of Information) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Medicare Promoting Interoperability Program.

In section IX.F.9.b. of the preamble of this proposed rule, we are proposing to adopt the Hospital Harm VTE eCQM and remove the VTE Prophylaxis and Intensive Care Unit VTE Prophylaxis eCQMs beginning with the CY 2028 reporting period. While there is no change in information collection burden associated with these proposals because the two current VTE eCQMs are available for CAHs to self-select to meet reporting requirements and the proposed Hospital Harm VTE eCQM would also be available for CAHs to self-select (we note that it would become mandatory after two years if the proposal to require Hospital Harm eCQMs after two years of self-selected reporting is finalized), we note that there would be a reduction in administrative burden as the proposals would result in replacing two process measures with a single comprehensive outcome measure. Additionally, in section IX.B.1. of the preamble of this proposed rule, we are proposing to adopt the Advance Care Planning eCQM beginning with the CY 2028 reporting period, for which there is also no change in information collection burden. Regarding administrative costs associated with adoption of eCQMs, we believe they are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in EHR systems for the eCQMs used in the program.

In section IX.F.4. of the preamble of this proposed rule, we are proposing to remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2028. If finalized, eligible hospitals and CAHs currently reporting these measures would be required to instead report either the Health Information Exchange (HIE) Bi-Directional Exchange measure or the Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) measure. Based on Medicare Promoting Interoperability Program data from the EHR reporting period in CY 2024, the

26.6 percent of eligible hospitals and CAHs that reported on the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures may incur some onboarding labor and vendor costs associated with the process to plan, procure, configure, and validate new workflows as well as the transition to set up and technically validate the functioning of the information exchange. In addition, eligible hospitals and CAHs may also incur some recurring costs associated with joining a health information exchange or TEFCA QHIN, such as annual subscription fees, transaction fees, or vendor and maintenance support, depending on the nature of their agreement with health IT vendors or other entities through which they participate in TEFCA. However, because each eligible hospital, CAH, and health IT vendor or other entity is unique and we lack sufficient insight into the individual decisions of each, the extent of these costs is difficult to quantify. Published literature largely does not evaluate the costs and benefits associated with HIE or TEFCA adoption in any detail, although some published papers indicate a mixture of both cost benefits and savings associated with HIE adoption.<sup>573 574</sup> We seek public comments describing the direct costs and benefits associated with HIE or TEFCA adoption because it may improve our ability to quantify the financial impacts for eligible hospitals and CAHs affected by the proposal.

We do not believe the remaining provision results in any additional economic impact beyond those discussed in section XII.B.7. of the preamble of this proposed rule.

#### *O. Alternatives Considered*

This proposed rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

##### **1. Alternatives Considered to the LTCH QRP Reporting Requirements**

With regard to the proposals to remove both the COVID–19 Vaccination

Coverage among Healthcare Personnel (HCP) and COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, we considered keeping both measures. However, when these measures were adopted, there were well-defined parameters for receiving the COVID–19 vaccination. We determined that these measures no longer align with current clinical guidelines and therefore the publicly reported measures may not reliably give consumers information on the number of HCP that are vaccinated, or the percent of stays in which patients in an LTCH are up to date on their COVID–19 vaccinations.

With regard to the proposal to revise the LTCH QRP assessment data submission deadline from 4.5 months to 45 days, we considered keeping the deadline unchanged. We determined that 45 days is a reasonable amount of time for LTCHs to submit data and make any necessary corrections, and that the benefits of this shortened timeframe include making the data timelier and more actionable which increases the value of publicly reported data, both for consumers and their families and for LTCHs to use in their quality improvement activities.

##### **2. Alternatives Considered for the Transforming Episode Accountability Model**

In section X.A. of the preamble of this proposed rule, we discuss the mandatory episode-based payment model called the Transforming Episode Accountability Model (TEAM). TEAM is designed to improve beneficiary care through financial accountability for episodes categories that begin with one of the following procedures: coronary artery bypass graft, lower extremity joint replacement, major bowel procedure, surgical hip/femur fracture treatment, and spinal fusion. TEAM will test whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate that TEAM would benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode.

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered and provided information as to the effects of these alternatives and

<sup>573</sup> Menachemi N, Rahurkar S, Harle CA, Vest JR. The benefits of health information exchange: an updated systematic review. *Journal of the American Medical Informatics Association*. 2018 Sep;25(9):1259–65.

<sup>574</sup> Everson J, Chang W, Patel V, Adler-Milstein J. The state of health information organizations and plans to participate in the federal exchange framework. *Health Affairs Scholar*. 2024 Aug;2(8):qxae098.

the rationale for each of the proposed policies. For example, in section X.A.2.c.(2).(c). of the preamble of this proposed rule we considered removing the 3 percent cap on the retrospective trend factor to account for MS–DRG and HCPCS–APC changes that may occur after preliminary target prices are released. However, we are concerned that removing the cap on the retrospective trend factor would introduce target price instability and would present challenges for TEAM participants to predict performance in the model.

We solicit and welcome comments on our proposals, on the alternatives we have identified, including starting the proposed changes for MS–DRG and APC update factors in performance year 2, as discussed in section X.A.2.c.(2). of the preamble of this proposed rule, and on other alternatives that we should consider.

### 3. Alternatives Considered for the Comprehensive Care for Joint Replacement Expanded (CJR–X) Model

In section X.C. of this proposed rule, we are proposing the Comprehensive Care for Joint Replacement Expanded (CJR–X) Model to build upon the Comprehensive Care for Joint Replacement (CJR) Model that was tested from April 1, 2016 to December 31, 2024. Based on the strength of evidence from the CJR Model test, the Innovation Center is proposing to expand the model to all acute care hospitals in the 50 United States, District of Columbia, and U.S. Territories, except for hospitals participating in the Transforming Episode Accountability Model (TEAM) and hospitals located in Maryland. CJR–X would include several updates to the CJR Model. We propose that the model would begin October 1, 2027 (FY 2028).

The model would focus on improving care and reducing spending for Medicare beneficiaries undergoing lower extremity joint replacement (LEJR) procedures. Participant hospitals would be held accountable for spending and quality of care during an initial LEJR admission and for the 90 days following hospital discharge. Throughout the proposed rule, we identify proposed policies and any alternatives considered. We provide background and rationale for each of the proposed policies and discussion of alternative policies including their potential effects. For example, we considered several original CJR quality reporting and payment methodology policies but ultimately proposed updates in response to the CJR Model evaluation results, stakeholder feedback,

and changes to national care delivery patterns among both CJR and non-CJR hospitals. Throughout the preamble, we solicit comments on our proposals, alternatives policies, and other options we should consider.

### P. Overall Conclusion

#### 1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately \$1.9 billion in FY 2027, including operating, capital, and the effects of: (1) new technology add-on payment changes; (2) the changes to estimated uncompensated care payments; and (3) the statutory expiration of the MDH program and the temporary changes to the low-volume hospital payment adjustment on January 1, 2027. The estimated change in operating payments including outlier payments, and uncompensated care payments is approximately \$1.5 billion (discussed in sections I.F of this Appendix). The estimated change in capital payments is approximately \$0.18 billion (discussed in section I.I. of this Appendix). The estimated change in the combined effects of other proposed changes including new technology add-on payment changes and the statutory expiration of the temporary changes to the low-volume hospital payment adjustment on January 1, 2027, is approximately \$0.18 billion as discussed in sections I.F and I.G. of the Appendix of this proposed rule. Totals may differ from the sum of the components due to rounding.

Table I. of section I.F. of the Appendix and Table III of section I.I. of this Appendix of this proposed rule also demonstrates the estimated redistributional impacts of the proposed FY 2027 changes on IPPS operating and capital payments, respectively, relative to FY 2026. The discussions presented in the previous pages, in combination with the remainder of this proposed rule, constitute a regulatory impact analysis.

#### 2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments in FY 2027. In the impact analysis, we are using the rates, factors, and policies presented in this proposed rule based on the best available data to estimate the change in payments under the LTCH PPS for FY 2027. Accordingly, based on the best available data for the 318 LTCHs included in our analysis, we estimate that aggregate FY 2027 LTCH PPS payments to LTCH PPS standard Federal payment rate cases would increase approximately \$55

million relative to FY 2026, primarily due to the proposed annual update to the LTCH PPS standard Federal rate.

### Q. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We recognize that different types of entities are in many cases affected by mutually exclusive sections of the rule. Thus, for the purposes of our estimate we assume that each reviewer read approximately 50 percent of the proposed rule. Finally, in our estimates, we have used the 5,409 number of timely pieces of correspondence on the FY 2026 IPPS/LTCH PPS proposed rule as our estimate for the number of reviewers of this rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is \$113.42 per hour, including overhead and fringe benefits ([https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm)). Assuming an average reading speed, we estimate that it would take approximately 17.42 hours for the staff to review half of this proposed rule. For each IPPS hospital or LTCH that reviews this proposed rule, the estimated cost is \$1,975.78 (17.42 hours × \$113.42). Therefore, we estimate that the total cost of reviewing this proposed rule is

\$10,686,994 (\$1,975.78 × 5,409 reviewers).

## II. Accounting Statements and Tables

### A. Acute Care Hospitals

As required by OMB Circular A–4 (available at <https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf>) in Table V.

of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented

in this proposed rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of the Appendix of this proposed rule, the net costs to the Federal Government associated with the policies in this proposed rule are estimated at \$1.9 billion.

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**TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2026 TO FY 2027**

| Category                       | Transfers                                     |
|--------------------------------|-----------------------------------------------|
| Annualized Monetized Transfers | \$1.9 billion                                 |
| From Whom to Whom              | Federal Government to IPPS Medicare Providers |

### B. LTCHs

As discussed in section I.J. of the Appendix of this proposed rule, the impact analysis of the payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2027 relative to FY 2026 of approximately \$55 million based on the data for 318 LTCHs in our analysis.

Therefore, as required by OMB Circular A–4 (available at <https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf>), in Table VI. of the Appendix of this proposed rule, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate LTCHs. Table VI. of this Appendix provides our best estimate of the estimated change in Medicare payments under the LTCH

PPS as a result of the payment rates and factors and other provisions presented in this proposed rule based on the data for the 318 LTCHs in our analysis. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of the Appendix of this proposed rule, the net cost to the Federal Government associated with the policies for LTCHs in this proposed rule are estimated at \$55 million.

**TABLE VI.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2026 LTCH PPS TO THE FY 2027 LTCH PPS**

| Category                       | Transfers                                     |
|--------------------------------|-----------------------------------------------|
| Annualized Monetized Transfers | \$55 million                                  |
| From Whom to Whom              | Federal Government to LTCH Medicare Providers |

### C. Quality Reporting Programs

As required by OMB Circular A–4 (available at <https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf>) in Table V. of this Appendix, we have prepared an

accounting statement showing the classification of the costs associated with the provisions of this proposed rule as they relate to the following quality reporting programs: Hospital Inpatient Quality Reporting Program,

PPS-Exempt Cancer Hospital Quality Reporting Program, Medicare Promoting Interoperability Program and the Long-Term Care Hospital Quality Reporting Program.

**TABLE VII.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS RELATED TO THE VARIOUS QUALITY REPORTING PROGRAMS**

| Hospital Quality Burden Costs, CYs 2026-2030 |                  |                  |
|----------------------------------------------|------------------|------------------|
| Category                                     | Primary Estimate |                  |
| Costs                                        | 3% Discount Rate | 7% Discount Rate |
| Annualized Monetized Net Costs               | \$0.1 million    | \$0.09 million   |

*D. Non-Renal Organ Acquisition Costs for Independent Organ Procurement Organizations and Histocompatibility Laboratories*

As required by OMB Circular A–4 (available at <https://www.reginfo.gov/>

[public/jsp/Utilities/a-4.pdf](#)) in Table V. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures and costs associated with the provisions of this proposed rule as they relate to non-

renal organ acquisition costs for independent organ procurement organizations, and histocompatibility laboratories.

**TABLE VIII.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES AND COSTS**

| Non-Renal Organ Acquisition Costs for Independent Organ Procurement Organizations FYs, 2027-2036 |                                     |                  |
|--------------------------------------------------------------------------------------------------|-------------------------------------|------------------|
| Category                                                                                         | Transfers                           |                  |
| Costs                                                                                            | 3% Discount Rate                    | 7% Discount Rate |
| Annualized Monetized Transfers                                                                   | -\$124.7 million                    | -\$120.4 million |
| From Whom to Whom                                                                                | Federal Government to Medicare OPOs |                  |
| Burden Reporting Costs to OPOs and HCLs, FY 2028                                                 |                                     |                  |
| Category                                                                                         | Primary Estimate                    |                  |
| Annualized Monetized Costs                                                                       | \$73,828                            |                  |

**III. Regulatory Flexibility Act (RFA) Analysis**

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business economy. Hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business

Administration (SBA) definition of a small business (having revenues of less than \$9.0 million to \$47.0 million in any 1 year). (For details, see the SBA's website at <http://www.sba.gov/content/small-business-size-standards> (refer to the 620000 series or Sector 62, Health Care and Social Assistance).)

We utilized the NAICS U.S. industry title “Hospitals” and corresponding NAICS code 622 in determining impacts for small entities for this rule. The NAICS code 622 has a size standard of \$47 million.<sup>575</sup> Table VII shows the

<sup>575</sup> [https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards\\_Effective%20March%2017%2C%202023%20%281%29%20%281%29\\_0.pdf](https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%281%29%20%281%29_0.pdf).

number of firms, revenue, and estimated impact per hospital category.

For purposes of the RFA, approximately half of all hospitals are considered to be small entities. As shown in Table IX, hospitals with enterprise size of \$49 million or less (1,494) are approximately 48 percent of total firms (3,136). Because roughly half of hospitals qualify as small entities under the RFA, the impacts described in this proposed rule generally affect small entities. Individuals and States are not included in the definition of a small entity. MACs are also not considered to be small entities because they do not meet the SBA definition of a small business.

**TABLE IX: NUMBER OF FIRMS, REVENUE, AND AVERAGE REVENUE PER FIRM OF HOSPITALS FOR NAICS CODE 622**

| NAICS | NAICS Description | Enterprise Size (\$1,000) | Number of Firms | Receipts (\$1,000) | Average Receipts Per Firm (\$1,000) |
|-------|-------------------|---------------------------|-----------------|--------------------|-------------------------------------|
| 622   | Hospitals         | <100                      | 68              | 3,235              | 48                                  |
| 622   | Hospitals         | 100-499                   | 176             | 47,198             | 268                                 |
| 622   | Hospitals         | 500-999                   | 61              | 43,484             | 713                                 |
| 622   | Hospitals         | 1,000-2,499               | 36              | 55,875             | 1,552                               |
| 622   | Hospitals         | 2,500-4,999               | 43              | 160,867            | 3,741                               |
| 622   | Hospitals         | 5,000-7,499               | 45              | 285,858            | 6,352                               |
| 622   | Hospitals         | 7,500-9,999               | 77              | 653,169            | 8,483                               |
| 622   | Hospitals         | 10,000-14,999             | 158             | 1,852,000          | 11,722                              |
| 622   | Hospitals         | 15,000-19,999             | 173             | 2,919,720          | 16,877                              |
| 622   | Hospitals         | 20,000-24,999             | 154             | 3,391,347          | 22,022                              |
| 622   | Hospitals         | 25,000-29,999             | 128             | 3,342,680          | 26,115                              |
| 622   | Hospitals         | 30,000-34,999             | 126             | 3,876,502          | 30,766                              |
| 622   | Hospitals         | 35,000-39,999             | 87              | 3,061,225          | 35,186                              |
| 622   | Hospitals         | 40,000-49,999             | 162             | 6,839,652          | 42,220                              |
| 622   | Hospitals         | 50,000+                   | 1,642           | 1,328,006,166      | 808,774                             |
| 622   | Hospitals         | Total                     | 3,136           | 1,354,538,978      | 431,932                             |

**Source:** Data obtained from United States Census Bureau table “us\_6digitaics\_rptsiz\_2022” (SOURCE: 2022 SUSB Annual Data Tables by Establishment Industry) Release Date: 4/10/2025: [https://www2.census.gov/programs-surveys/susb/tables/2022/us\\_6digitaics\\_rptsiz\\_2022.xlsx](https://www2.census.gov/programs-surveys/susb/tables/2022/us_6digitaics_rptsiz_2022.xlsx).

**Notes:** The ‘Average Receipts Per Firm’ is calculated as the Receipts (\$1,000)/Number of Firms. The ‘Total’ row represents all the hospital firms under NAICS 622. Overall receipts (revenue) for the 3,136 firms (NAICS 622) are approximately \$1,355 billion.

**TABLE VIII: ESTIMATED IMPACT ON SMALL BUSINESSES\***

|                       | Total Facilities | Estimated Small Businesses | Total Impact (\$1 million) | Estimated Impact to Small Businesses | Estimated Average Impact per Small Business |
|-----------------------|------------------|----------------------------|----------------------------|--------------------------------------|---------------------------------------------|
| <b>IPPS Hospitals</b> | 3,013            | 1,389                      | \$1,900                    | \$34,300,000                         | \$24,727                                    |
| <b>LTCHs</b>          | 318              | 147                        | \$55                       | \$994,029                            | \$6,782                                     |

\* Based on the assumptions that small firms represent 46.1 percent of affected entities and account for approximately 1.8 percent of total industry revenues using the SBA size standards.

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HHS interprets the RFA to consider economic effects “significant” when more than 5 percent of providers incur impacts of at least 3 to 5 percent or more of total revenue or total costs. Approximately 44 percent of Medicare-participating hospitals report Medicare utilization of at least 25 percent of their total inpatient days (see the “Medicare Utilization as a Percent of Inpatient Days” category in Table I in section I.F. of the Appendix to this proposed rule), indicating that Medicare payments constitute a substantial portion of hospital revenue. In addition, approximately 5 percent of hospitals qualify as MDHs and report Medicare utilization at least 60 percent of the

hospital’s inpatient days or discharges. Based on this analysis, we estimate that the policies proposed in this rule would affect more than 5 percent of hospitals with changes in Medicare revenue of at least 3 to 5 percent.

For example, we estimate that a majority of the 3,013 IPPS hospitals included in the impact analysis presented in “Table I.—Impact Analysis of Proposed Changes to the IPPS for Operating Costs for FY 2027” would experience average payment increases of approximately 1.2 percent. We attribute these increases primarily to the proposed outlier payments, the proposed hospital rate update, and the proposed uncompensated care

payments, as described in section I.F. of the Appendix to this proposed rule. Across hospital categories, we estimate that impacts would range from an increase of 3.3 percent for urban New England hospitals to a decrease of 7.6 percent for MDHs, as described in section I.F. of the Appendix to this proposed rule.

We project that LTCHs would experience overall an increase in payments for LTCH PPS standard Federal payment rate cases in FY 2027. In this impact analysis, we use the rates, factors, and policies proposed in this rule, based on the best available data, to estimate payment changes for FY 2027. Accordingly, using the best available

data for the 318 LTCHs included in our analysis, we estimate that LTCH PPS payments for LTCH PPS standard Federal payment rate cases would increase approximately \$55 million relative to FY 2026, primarily due to the proposed annual update to the LTCH PPS standard Federal rate.

We further estimate that the 318 LTCH PPS hospitals included in the impact analysis presented in “Table IV: Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2027 (Estimated FY 2026 Payments Compared to Estimated FY 2027 Payments)” would experience an average increase of approximately 2.3 percent. We attribute this increase primarily to the proposed annual standard Federal rate update of 2.4 percent for FY 2027, as discussed in section I.J. of the Appendix to this proposed rule. Across LTCH categories, we estimate that impacts would range from an increase of 3.9 percent for government-owned LTCHs to an increase of 1.7 percent for rural LTCHs, as described in section I.J. of the Appendix to this proposed rule.

As shown in Tables V. and VI. of this Appendix, we estimate that this proposed rule will result in aggregate transfers of approximately \$1.9 billion to IPPS hospitals and \$55 million to LTCHs. In Table IX., we estimate the impact of this rule on small entities by applying the SBA size standards and approximating the share of affected firms and revenues attributable to small entities. Specifically, we assume that small firms represent 46.1 percent of affected entities and account for approximately 1.8 percent of total industry revenues. Using these assumptions, we estimate that of the 3,013 IPPS hospitals, approximately 1,389 are small entities, and of the 318 LTCHs, approximately 147 are small entities. Applying the 1.8 percent revenue share, we estimate that approximately \$34.3 million of the IPPS impacts and approximately \$1.0 million of the LTCH impacts would accrue to small entities, which corresponds to an average impact of approximately \$24,727 per small IPPS hospital and approximately \$6,782 per small LTCH.

This proposed rule includes a range of proposals. We describe the applicable statutory provisions, identify the proposed policies, present the rationale for these proposals, and, where appropriate, the alternatives considered. Rationales for various proposals are outlined in the Statement of Need in section I.A. of the Appendix to this proposed rule. For example, under the

statutory requirement at section 1886(b)(3)(B) of the Act, we propose to update the national standardized amount for inpatient hospital operating costs by the applicable percentage increase of 2.4 percent, as described in section I.A. of the Appendix to this proposed rule, and we did not consider an alternative for small businesses. Alternatives considered for various proposals are described in section I.O. of the Appendix to this proposed rule.

The analyses presented in this Appendix and throughout the preamble of this proposed rule constitute our initial regulatory flexibility analysis. We invite public comment on our estimates and our assessment of the impact of the proposed policies on small entities.

#### **IV. Impact on Small Rural Hospitals**

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals.

As shown in Table I. in section I.F. of the Appendix of this proposed rule, rural IPPS hospitals with 0–49 beds (316 hospitals) are expected to experience a decrease in payments from FY 2026 to FY 2027 of 0.7 percent and rural IPPS hospitals with 50–99 beds (175 hospitals) are expected to experience a decrease in payments from FY 2026 to FY 2027 of 0.3 percent. These changes are primarily driven by the proposed hospital rate update and the increase in estimated uncompensated care payment offset by the statutory expiration of the MDH program and the budget neutral changes to the MS–DRGs and relative weights. We refer readers to Table I. in section I.F. of the Appendix of this proposed rule for additional information on the quantitative effects of the proposed policy changes under the IPPS for operating costs.

All rural LTCHs (16 hospitals) shown in Table IV. in section I.J. of the Appendix of this proposed rule have less than 100 beds. These hospitals are

expected to experience an increase in payments from FY 2026 to FY 2027 of 1.7 percent. This increase is primarily due to the proposed 2.4 percent annual update to the LTCH PPS standard Federal payment rate for FY 2027 being partially offset by a projected decrease in payments due to the proposed changes to the area wage level adjustment and the proposed changes to the MS–LTC–DRG classifications and relative weights.

#### **V. Unfunded Mandates Reform Act Analysis**

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately \$193 million. This proposed rule would not mandate any requirements that meet the threshold for State, local, or Tribal governments, nor would it affect private sector costs.

#### **VI. Executive Order 13132**

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts state law, or otherwise has federalism implications. This proposed rule would not have a substantial direct effect on State or local governments, preempt states, or otherwise have a federalism implication.

#### **VII. Executive Order 13175**

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having Tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian Tribe or Tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this proposed rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act. We continue to engage in consultations with Tribal officials on IPPS issues of interest. We use input received from these consultations, as

well as the comments on the proposed rule, to inform our rulemaking.

### VIII. Executive Order 14192

Executive Order 14192, titled “Unleashing Prosperity Through Deregulation,” was issued on January 31, 2025, and requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.

### Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

#### I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2027, consistent with our approach for FY 2026, we are including the Secretary’s recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response

to MedPAC’s recommended update factors for inpatient hospital services.

### II. Inpatient Hospital Update for FY 2027

#### A. Proposed FY 2027 Inpatient Hospital Update

As discussed in section VI.B. of the preamble to this proposed rule, for FY 2027, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket percentage increase or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket percentage increase or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then an adjustment based on changes in economy-wide productivity (the productivity adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2026

IPPS/LTCH PPS final rule (90 FR 36859 through 36879), we replaced the 2018 based IPPS operating and capital market baskets with the rebased and revised 2023-based IPPS operating and capital market baskets beginning in FY 2026.

In this FY 2027 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2027 market basket update used to determine the applicable percentage increase for the IPPS on IGI’s fourth quarter 2025 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through third quarter 2025, which is estimated to be 3.2 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section VI.B. of the preamble of this FY 2027 IPPS/LTCH PPS proposed rule, based on IGI’s fourth quarter 2025 forecast, we are proposing a productivity adjustment of 0.8 percentage point for FY 2027. We are also proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2027 market basket update and productivity adjustment for the FY 2027 IPPS/LTCH PPS final rule.

Therefore, based on IGI’s fourth quarter 2025 forecast of the 2023-based IPPS market basket percentage increase and the productivity adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we are proposing four possible applicable percentage increases that could be applied to the standardized amount, as shown in the table that follows.

| <b>FY 2027</b>                                                                                         | <b>Hospital Submitted Quality Data and is a Meaningful EHR User</b> | <b>Hospital Submitted Quality Data and is NOT a Meaningful EHR User</b> | <b>Hospital Did NOT Submit Quality Data and is a Meaningful EHR User</b> | <b>Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User</b> |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------|
| Proposed IPPS Market Basket Rate-of-Increase                                                           | 3.2                                                                 | 3.2                                                                     | 3.2                                                                      | 3.2                                                                          |
| Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act    | 0.0                                                                 | 0.0                                                                     | -0.8                                                                     | -0.8                                                                         |
| Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act | 0.0                                                                 | -2.4                                                                    | 0.0                                                                      | -2.4                                                                         |
| Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act                            | -0.8                                                                | -0.8                                                                    | -0.8                                                                     | -0.8                                                                         |
| Proposed Applicable Percentage Increase Applied to Standardized Amount                                 | 2.4                                                                 | 0.0                                                                     | 1.6                                                                      | -0.8                                                                         |



### *B. Proposed FY 2027 SCH and MDH Update*

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act.

As discussed in section VI.F. of the preamble of this proposed rule, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027. We refer readers to section V.E. of the preamble of this proposed rule for further discussion of the MDH program.

As previously stated, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs and MDHs.

### *C. Proposed FY 2027 Puerto Rico Hospital Update*

Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section VI.B.1. of the preamble of this proposed rule.

In addition, as discussed in section VI.B.2. of the preamble of this proposed rule, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under

section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022.

Section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that for FY 2024 and subsequent fiscal years, any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments).

Based on IGI's fourth quarter 2025 forecast of the 2023-based IPPS market basket update with historical data through third quarter 2025, in this FY 2027 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as previously discussed, for Puerto Rico hospitals, we are proposing an IPPS market basket increase of 3.2 percent and a productivity adjustment of 0.8 percentage point. Therefore, for FY 2027, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we are proposing the following applicable percentage increases to the standardized amount for FY 2027 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 2.4 percent (that is, the FY 2027 estimate of the proposed IPPS market basket rate-of-increase of 3.2 percent less an adjustment of 0.8 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 0.0 percent (that is, the FY 2027 estimate of the proposed market basket rate-of-increase of 3.2 percent, less an adjustment of 2.4 percentage point (the proposed IPPS market basket rate-of-increase of 3.2 percent  $\times$  0.75 for failure to be a meaningful EHR user), and less an adjustment of 0.8 percentage point for the proposed productivity adjustment).

As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2027 market basket percentage increase and the productivity adjustment for the FY 2027 IPPS/LTCH PPS final rule.

### *D. Proposed Update for Hospitals Excluded From the IPPS for FY 2027*

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this proposed rule, we are proposing to use the percentage increase in the 2023-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2027 and subsequent fiscal years. Accordingly, for FY 2027, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2027 percentage increase in the 2023-based IPPS operating market basket. For this proposed rule, the current estimate of the IPPS operating market basket percentage increase for FY 2027 is 3.2 percent. We are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2027

IPPS operating market basket rate-of-increase for the FY 2027 IPPS/LTCH PPS final rule.

#### *E. Proposed Update for LTCHs for FY 2027*

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2027 by 2.4 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the productivity adjustment). Furthermore, in accordance with the LTCH QRP under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are proposing to establish an update factor of 1.024 in determining the LTCH PPS standard Federal rate for FY 2027. For LTCHs that fail to submit quality data for FY 2027, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 0.4 percent (that is, the proposed annual update for FY 2027 of 2.4 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a proposed update factor of 1.004 in determining the LTCH PPS standard Federal rate for FY 2027. (We note that, as discussed in section IX.C. of the preamble of this proposed rule, the update to the LTCH PPS standard Federal payment rate of 2.4 percent for FY 2027 does not reflect any budget neutrality factors.)

### **III. Secretary's Recommendations**

MedPAC is recommending inpatient hospital rates be updated by the amount specified in current law. MedPAC's rationale for this update recommendation is described in more detail in this section. As previously stated, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and

effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 3.2 percent.

For FY 2027, consistent with policy set forth in section IX.C. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 2.4 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2027, we are recommending an annual update to the LTCH PPS standard Federal rate of 0.4 percent.

### **IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare**

In its March 2026 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates by the amount specified in current law. MedPAC anticipates that their recommendation to update the IPPS payment rate by the amount specified under current law in FY 2027 would generally be adequate to maintain beneficiaries' access to hospital inpatient and outpatient care and keep IPPS payment rates close to, if somewhat below, the cost of delivering high-quality care efficiently.

MedPAC recommends redistributing the current Medicare safety-net payments (disproportionate share hospital and uncompensated care payments) using the MedPAC-developed Medicare Safety-Net Index

(MSNI) for hospitals. In addition, MedPAC recommends adding \$1 billion to this MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to Congress transitional approaches for a MSNI policy.

We refer readers to the March 2026 MedPAC report, which is available for download at <https://www.medpac.gov/document-type/report/>. We look forward to working with Congress on these matters.

We are proposing an applicable percentage increase for FY 2027 of 2.4 percent as described in section 1886(b)(3)(B) of the Act, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. We note that, because the operating and capital payments in the IPPS remain separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

We note that section 1886(d)(5)(F) of the Act provides for additional Medicare payment adjustments, called Medicare disproportionate share hospital (DSH) payments, for subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. Section 1886(r) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay each such subsection (d) hospital that is eligible for Medicare DSH payments an empirically justified DSH payment equal to 25 percent of the Medicare DSH adjustment they would have received under section 1886(d)(5)(F) of the Act if subsection (r) did not apply. The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments if subsection (r) of the Act did not apply, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and has uncompensated care. These additional payments are called uncompensated care payments. We refer readers to section V. of the preamble of this proposed rule for further discussion of Medicare DSH and uncompensated care payments.

[FR Doc. 2026–07203 Filed 4–10–26; 4:15 pm]

BILLING CODE 4120–01–P